UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,	)	MD 15-02641-PHX-DGC
Lisa Hyde and Mark Hyde, a married couple,	)	Phoenix, Arizona **September 27, 2018**
Plaintiffs,	)	
v.	)	CV 16-00893-PHX-DGC
C.R. Bard, Inc., a New Jersey corporation, and Bard Peripheral Vascular, an Arizona corporation,	)	
Defendants.	)	

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

TRIAL DAY 8 - P.M. SESSION

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I N D E X

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P R O C E E D I N G S

(Proceedings resumed at 1:00 p.m.)

(Jury present.)

THE COURT: You may continue, Ms. Helm.

MR. ROGERS: Thank you, Your Honor.

LISA HYDE,

called as a witness herein by the plaintiffs, having been previously duly sworn or affirmed, resumed the stand and continued to testify as follows:

CROSS-EXAMINATION (Continued)

BY MS. HELM:

Q. Good afternoon, Ms. Hyde. I got it right this time.

A. Good afternoon.

Q. I want to follow -- just go back and start following up a little bit of your medical treatment that took place after the filter was implanted. So we're talking about after February of 2011, okay?

A. Okay.

Q. And in that time, you were living in Las Vegas; right?

A. Correct.

Q. And, really, since 2011, you and your husband and your youngest daughter have lived in Las Vegas; correct?

A. Yes.

Q. And you were getting medical care from medical care providers in Las Vegas; correct?

A. Correct.
Q. And you mentioned earlier originally your primary care provider was Dr. Sparks, and sometime in approximately 2014 you changed to Dr. Lehrner; is that right?
A. That is correct.
Q. And you've had Dr. Lehrner as your primary care provider for the last four years; correct?
A. Correct.
Q. Okay. And she knows about the history of your filter and that it was retrieved and that you went to Dr. Kuo; correct?
A. Yes.
Q. Okay. And you've also been under the care of a hematologist since approximately 2012; is that right?
A. That's right.
Q. And, I'm sorry, what is her name?
A. Her name is Dr. Thummala.
Q. Thank you for pronouncing that for me.
And Dr. Thummala is who prescribed you with the Xarelto; correct?
A. Correct.
Q. And she monitors your blood thinner to make sure that you're taking the appropriate dose; correct?
A. Correct.
Q. And she's been your doctor since -- for six years?
A. Since 2012, yes.

Q. So for six years; right?
A. Six years, correct.
Q. And she also knows about your filter and the fact that Dr. Kuo retrieved it; correct?
A. Correct.
Q. Okay. Let's back up.
After the filter was implanted, you had the misfortune of having kidney stones, didn't you?
A. Yes, I did.
Q. Those are incredibly painful, aren't they?
A. Yes, they are.
Q. Okay. And after the filter was implanted, you also were diagnosed with ovarian cysts and endometriosis, weren't you?
A. I had endometriosis from when I was younger. The cyst was on the one ovary. I already had one removed.
Q. And that was painful?
A. Not really at that point.
Q. Okay.
A. No.
Q. But it did result in a hysterectomy; correct?
A. For multiple reasons, yes.
Q. Yeah. Okay.
And in 2012, you slipped and fell. Do you remember that?
A. I didn't -- well, I didn't really fall. I was reaching --

MR. O'CONNOR: Excuse me, Your Honor.

False alarm. I apologize.

THE COURT: Okay. Go on, Ms. Helm.

BY MS. HELM:

Q. In 2012, you slipped and fell, correct, or you almost fell; correct?

A. Well, no. I had an SUV. I was reaching into the back. Instead of opening the trunk, I was in the back seat reaching for something that was in the trunk, and I just slipped onto the seat, the top of the seat. So I fell like 3 inches.

Q. But you went to the emergency room?

A. I did.

Q. And you were diagnosed with bruised ribs and a chest contusion; correct?

A. Correct.

Q. And then in 2013, you talked about this, you just weren't feeling good and Dr. Sparks diagnosed you with fibromyalgia; correct?

A. Correct.

Q. And she provided you with a prescription for Cymbalta; correct?

A. Correct.

Q. And you took the Cymbalta; correct?

A. Yes.

Q. And you got some relief from it; correct?

A. No.
Q. You got no relief?
A. No. In fact, the Cymbalta made me feel terrible.
Q. Okay. In 2013, you also went to see a neurologist, a Dr. Milford. Do you remember that?
A. Yes.
Q. And that was for neck and back pain?
A. Yes.
Q. And he diagnosed you with some issues in your neck; is that right?
A. Correct. Cervical stenosis.
Q. And sometime between 2011 and 2014, you were also diagnosed with diverticulitis. Do you remember that?
A. Yes.
Q. And when was that?
A. I believe that was in the summer of 2013.
Q. And, again, diverticulitis, that's an inflammation of your colon; correct?
A. Correct.
Q. And what were your symptoms that you had from the diverticulitis?
A. I had pain in my lower abdomen.
Q. And you didn't feel good, did you?
A. No.
Q. And what was the treatment for the diverticulitis?

A. Antibiotics and basically broth for four days.
Q. Okay. And you told Mr. O'Connor and the jury that in 2014 you went to see a cardiologist, Dr. Shehane. Do you recall that testimony?
A. Correct.
Q. And you went to Dr. Shehane two times; correct?
A. Correct.
Q. And since 2014, you have not been back to Dr. Shehane, have you?
A. No.
Q. And you haven't been to a cardiologist, have you?
A. No.
Q. Okay. And Dr. Lehrner, your primary care doctor, has not referred you to a cardiologist, has she?
A. No.
Q. And your hematologist, whose name I can't pronounce --
A. Thummala.
Q. Thank you.
-- Dr. Thummala has not referred you to a cardiologist, has she?
A. Not at this time.
Q. Okay. In 2016, you went to the emergency room at Summerlin Hospital. Do you recall that?
A. 2006 -- oh, yes. Yes.
Q. Where is Summerlin Hospital?

A. It's in Las Vegas.
Q. And you went to the hospital because you were having chest pain that was radiating up to your jaw; is that right?
A. That's right.
Q. Okay. And you went to the emergency room; is that right?
A. Yes.
Q. And they did a pretty thorough exam of you in the emergency room, didn't they?
A. Yes.
Q. They did CT scans; correct?
A. Correct.
Q. They did x-rays?
A. Yes.
Q. They did an EKG of your heart; correct?
A. Yes.
Q. They did a stress test; correct?
A. Correct.
Q. And all of those findings were normal. There were no cardiac issues; correct?
A. Correct.

MS. HELM: Thank you. No further questions.

THE COURT: Redirect?

MR. O'CONNOR: Yes, Your Honor.

REDIRECT EXAMINATION

BY MR. O'CONNOR:

Q. Just a couple, Lisa.

When you -- when Dr. Sparks thought you had fibromyalgia, did she send you to a rheumatologist?

A. She did.

Q. And did the rheumatologist confirm fibromyalgia?

A. No. He didn't think it was fibromyalgia.

Q. And after your filter went out -- I just want to talk about after those came out. You talked specifically about radiating pain down your leg before the filter. Do you recall that testimony?

A. Yes. Well, yeah, the front of my thighs were very painful.

Q. Did that go away?

A. Not entirely, but it's better.

Q. And what about the dizziness? Did that resolve?

A. That resolved, yes.

Q. Now, these other conditions you were asked about, did they necessitate any type of a -- well, you've had the issue way back when with the hysterectomy; correct?

A. Correct.

Q. When was that?

A. The hysterectomy was in April of 2012.

Q. Now, in terms of your doctors that you're seeing now, have any -- do you know if any of them have all the extent of the

medical records that people like Dr. Muehrcke have reviewed?
A. I don't know.
Q. And in terms of -- you're seeing these doctors for very specific conditions; correct?
A. Correct.
Q. And your hematologist is treating you for your blood disorder?
A. Yes.
Q. And, by the way, since you've had the filter taken out by Dr. Kuo, and that piece from your heart, have you ever had another PE?
A. No.
Q. The sleep problems that you have now, are they different from the sleep apnea?
A. They're very different.
Q. How so?
A. Well, when I first was diagnosed with sleep apnea, I would wake up in the night. I believe it was my body waking myself up because I stopped breathing every hour. But I think they said 11 times an hour. And that was just waking up.

This is more of a feeling that I'm dying or I'm dead, and I wake up in a panic and I literally have to jump out of bed, oftentimes taking that CPAP with me to the ground. But, yes, it's very different.
Q. And you -- in your medical history, did you ever think you

would ever have to see a doctor about care due to a strut in your heart being removed?

A. No.

MR. O'CONNOR: All right. That's all I have. Thank you.

THE COURT: All right. Thanks.

You can step down, Mrs. Hyde.

(Witness excused.)

MR. O'CONNOR: Thank you, Your Honor.

At this time, the plaintiffs rest, Your Honor.

THE COURT: All right. Plaintiffs have rested.

Defense counsel, your opportunity to present evidence.

MR. ROGERS: Yes, Your Honor. I do want to note for the record that we are -- what we discussed yesterday, that we do have a Rule 50 motion.

THE COURT: Right.

MR. ROGERS: But as I understand, that is preserved.

THE COURT: Yeah, that's being made. We can talk about that later when we're not keeping the jury waiting.

MR. ROGERS: Absolutely, Your Honor. I just wanted to note that for the record.

THE COURT: All right.

MR. ROGERS: So, Your Honor, at this time, the defendants would call Chad Modra.

THE COURT: Mr. Modra, you're still under oath for

purposes of the trial, so you can come directly back to the witness stand.

THE WITNESS: Thanks.

MS. HELM: May I proceed?

THE COURT: You may.

MS. HELM: Thank you, Your Honor.

CHAD MODRA,

called as a witness herein by the defendants, having been previously duly sworn or affirmed, was examined and testified as follows:

DIRECT EXAMINATION

BY MS. HELM:

Q. Good afternoon, Mr. Modra.

A. Good afternoon.

Q. Welcome back.

A. Thanks.

Q. Will you remind the jury how long you've worked at Bard?

A. 18 years.

Q. And in those 18 years, have you always been at Bard Peripheral Vascular?

A. No. I worked at another division of Bard, at another -- in another state.

Q. And what division is that?

A. It was called Bard Access Systems.

Q. And where is Bard Access Systems?

A. In Salt Lake City, Utah.
Q. And what type of products does Bard Access Systems make?
A. They designed and made implantable ports for cancer treatment, dialysis catheters, vascular access devices that go in the lower arm and upper arm.
Q. And when did you transfer from Bard Access Systems to Bard Peripheral Vascular?
A. In March 2011.
Q. From March 2011 till when were you with Bard Peripheral Vascular?
A. December 2015.
Q. And what role did you take in December of 2015? How did your job change?
A. I went from Bard Peripheral Vascular quality to staff vice president of quality at -- working at the Murray Hill, New Jersey, office.
Q. For C.R. Bard?
A. For C.R. Bard.
Q. And I understand you're starting a new job next week for C.R. Bard -- I'm sorry, for Bard Peripheral Vascular. You're coming back; correct?
A. I am. I am. I'm taking a role of strategic project manager.
Q. At one point you were -- you had the title vice president of quality for -- and when I refer to BPV, that's Bard

Peripheral Vascular; right?
A. Correct.
Q. And no one wants to listen to me stumble over that three times.
A. Right.
Q. So when were you -- when were you named vice president of quality at BPV?
A. In 2011.
Q. And when you became vice president of quality, were you responsible for the quality -- for the quality function, which we'll talk about, for a number of products, including IVC filters?
A. Yes. All the products that they had at the time.
Q. And what were those?
A. Angioplasty balloons, implantable stents, biopsy devices, biopsy needles, capital equipment, meaning things that are electronic.
Q. And would you just describe for the jury, you have this title vice president of quality. What were your -- what was your role and what were your responsibilities?
A. Well, as the vice president of quality, I interfaced most often with the rest of the functions throughout the business, meaning research and development, regulatory, clinical, the president of the division as well as marketing, sales, and manufacturing.

And my role is, although peers, a bit of independence because I know the most about the requirements, the regulation, the global regulation, so I was responsible for overseeing the procedures that we have there, writing them, modifying them, adapting those, and then ensuring that myself and the department are playing a role with each one of those functions in following the procedures.

Q. Let's learn a little bit about you before we get into your role as vice president of quality.

Where did you grow up?

A. In the Midwest, in -- north of Chicago.

Q. And you live in the Phoenix area now?

A. I do.

Q. And have you been in the Phoenix area since 2011?

A. March of 2011.

Q. And even with the job change with your responsibilities in New Jersey, you stayed in Phoenix?

A. Yes.

Q. Okay. Are you married?

A. I am.

Q. And in your spare time, what do you like to do?

A. Hike, run, photography.

Q. And are you involved in the community in any way?

A. Yeah. I have several areas where I volunteer.

Q. And what are those?

A. Through my church, through refugee associations, through helping with -- I teach little kids, 3- and 4-year-olds.
Q. And you teach them English?
A. I teach the adults English, and then my wife and I teach the 3- and 4-year-olds Sunday school.
Q. Okay. Thank you.
And you're an engineer?
A. I am. Mechanical.
Q. And from where did you -- did you receive a degree in mechanical engineering?
A. I did. Bachelor of Science in mechanical engineering from Purdue.
Q. And how long have you worked -- we've heard a lot about the medical device industry. We know your work with Bard, but how long have you worked in the medical device industry?
A. 24 years.
Q. Is that your entire professional career?
A. It is.
Q. And prior to Bard, where did you work?
A. I worked for Abbott Laboratories.
Q. And did you start at Abbott Laboratories in 1994?
A. I did. I actually started as an intern during summers while still in school a couple years prior to that. But I got a permanent job with Abbott in '94.
Q. And what type of product does Abbott Lab manufacture?

A. At the time, I worked in the medical devices area and also the nutritionals. So I was a quality engineer that supported manufacturing of baby formula. So I learned about high-volume manufacturing of baby formula and then spent time at different locations learning about medical devices that they had had, cardiac catheters being one of them.

Q. And when you transferred -- when you changed jobs to Bard in 2000 and went to Bard Access Systems, were you -- what was your role? What was your title?

A. I was a quality engineer in the new product development area, because I had spent five-plus years in manufacturing, knowing a lot about the manufacturing of difficult-to-make products, cardiac catheters. And I wanted to do something more in research and development.

Q. So --

A. New products.

Q. So you -- when you started at Bard Access, you were actually in the research and development group?

A. I was the quality engineer for research and development teams.

Q. Let's talk about that just a minute.

There's a -- and the jury's heard from a couple of engineers. There are engineers whose jobs are to develop, test -- to get a concept of, test, and hopefully launch a new product; is that right?

A. Yes.
Q. And those engineers, we've heard from Mr. Carr, for example. Those folks at Bard -- and Mr. Randall -- those folks at Bard, that's what they do; right?
A. Correct.
Q. In your role as a quality engineer, what is your role -- when you were doing research -- when you were working in the new product development, what was your role as a quality engineer in the new product development?
A. My role then and what I talk to quality engineers now is giving -- mentoring -- is you're the customer. You're the patient advocate. Quality engineers have the same skill sets as other engineers, but they are familiar with root cause investigation, quality tools, meaning they might be versed in FMEA writing and speaking to the customers; being part of the team but being independent and bringing a different voice to that. It helps improve the designs.
Q. So checks and balances for the design team?
A. Yeah.
Q. Okay. How many product launches -- how many developments into product launches were you involved with as a product engineer?
A. Across 11 years, I would guess over a hundred.
Q. Okay.
A. I mean, of any -- of a wide variety; implantable devices,

dialysis catheters, some of the most innovative that we had had at Bard at the time.

Q. And when you transferred from Bard Access to BPV, did you immediately come in as vice president of quality?

A. I came in as a board member at BPV, and then my title was converted to vice president shortly thereafter. But I was a director at the time.

Q. Responsible for the quality functions of the company; right?

A. Correct. Of the -- of the division.

Q. Of Bard -- I'm not going to do it.

A. BPV.

Q. BPV.

A. Yeah.

Q. Okay. Now, we talked about you've dedicated your entire professional career to the development or quality function of medical devices. Why did you decide to go into the medical device industry?

A. Although it can be really challenging, I mean, the great thing about a medical device industry is that you're making things. You're developing new things, and you -- the end result is helping people. I mean, you can make things that -- for other purposes in other industries, but medical devices, you get feedback. You get letters. I've gotten letters from customers. I've gone out and spoken to customers, to patients,

and so that's very rewarding, you know, despite, you know, the stresses of any engineering job.

Q. And we're going to talk some more about the stresses of the engineering job and the product development.

And the jury's heard a little bit about risk and benefit. And as an engineer, or as -- responsible for quality of medical devices, and particularly IVC filters, are "risk" and "benefit" terms that you use every day?

A. Yes.

Q. And are the engineers and the quality folks constantly and continuingly monitoring, evaluating, and analyzing the risks that come with implantable devices such as IVC filters versus the benefits they provide to patients?

A. You have to. Yes, we are. I mean, that's the purpose of it is that device is going to bring a benefit, a significant benefit. And so our job is to identify the risks, identify the benefits, and reduce the risks as much as possible.

Q. Based on your role in the quality department and your role as vice president of quality for BPV, do you believe that Bard's IVC filters provide an important therapeutic option for patients?

A. Of course. Yes.

Q. And based on your experience working at BPV in the quality role, what diseases, what conditions are IVC filters tended -- intended to treat?

A. DVT and also pulmonary embolism. And in the -- for indications, when a patient isn't indicated for anticoagulants, meaning blood thinners.
Q. Are they also therapeutic treatment for patients who maybe need more than just anticoagulants because they've had a history of PE?
A. Yes.
Q. Okay.
A. Yes.
Q. And is that something you've learned over the last several years in working with IVC filters?
A. Yes. Yes.
Q. Earlier today, the jury heard about a Surgeon General's Call to Arms about pulmonary embolism. Are you familiar with that?
A. I am.
Q. And as vice president of quality dealing -- responsible for IVC filters, you have an understanding that a blood clot, a DVT, can turn into a pulmonary embolism which can travel to someone's heart or lungs; correct?
A. Yes.
Q. And have you learned through your work at Bard what can happen if a pulmonary embolism travels to someone's heart or lungs?
A. Yes. It can result in death.

Q. And did you -- have you had an opportunity to review the Surgeon General's Call to Action that he -- that was issued in 2008 about pulmonary embolism?
A. Yes.
Q. Are you familiar with it as part of your job?
A. Yes.
MS. HELM: Scott, could we pull up 7411, please?
Your Honor, this is in evidence. May I publish?
THE COURT: Yes.
MS. HELM: Thank you.
BY MS. HELM:
Q. Mr. Modra, we were talking about the Surgeon General's Call to Action. And would you tell the ladies and gentlemen of the jury, is this the document that the Surgeon General of the United States published in 2008 regarding deep vein thrombosis and pulmonary embolism?
A. Yes.
Q. And this is a public record; right?
A. Yeah. It's available on the website.
Q. It's now available on their website. Thank you.
And in this document -- have you read it?
A. Yes.
Q. More than once?
A. More than once.
Q. Okay. Does the Surgeon General in this Call to Action

estimate rates of DVT and PE?
A. Yes.
MS. HELM: Scott, could you turn to page 9, please. And could you highlight the first paragraph, please.
BY MS. HELM:
Q. And, Mr. Modra, would you tell the ladies and gentlemen of the jury what the Surgeon General estimates as to how many people in America, just in the United States, each year suffer from DVT or pulmonary embolism?
A. Somewhere between 350,000 and 600,000.
Q. And can you tell the ladies and gentlemen of the jury what the Surgeon General estimates as to how many people die each year in America due to DVT or pulmonary embolism?
A. A hundred thousand.
Q. As much as -- as much as 30 percent?
A. Right.
Q. I'm not a good math person --
A. Right. Yeah.
Q. -- but as much as 30 percent; right?
A. Uh-huh. Yep.
Q. Okay. Thank you.
And does the Surgeon General recognize the importance of trying to prevent or treat DVT and PE?
A. They do by publishing this kind of document is what they're saying.

Q. And this is a document available to the medical community?
A. Yes.
Q. Available to the public in general?
A. Yes.
Q. And obviously available to companies like Bard?
A. Correct.
Q. Okay. And in this document, does the Surgeon General also recognize that IVC filters may be an appropriate treatment for PE or DVT?
A. Later on in the document, it says that they're an important part of the --
MS. HELM: Scott, could you go to page 25, please.
THE WITNESS: -- considerations.
MS. HELM: And could you highlight, on the right side, the paragraph that starts "Another preventative therapy."
BY MS. HELM:
Q. And is this the statement where the Surgeon General has recognized in 2008 that another preventative therapy option is the use of a retrievable implantable filter in the vena cava?
MR. O'CONNOR: Objection. Leading.
THE COURT: Well, it is leading.
MR. O'CONNOR: And cumulative.
THE COURT: Sustained on leading.
BY MS. HELM:
Q. What does the Surgeon General say about IVC filters for the

treatment or a therapy option for DVT or PE, Mr. Modra?
A. Another preventative therapy option is the use of a permanent or retrievable implantable filter.
Q. Will an IVC filter prevent a DVT from occurring?
A. No. It states that towards the bottom there.
Q. Okay. So the Surgeon General recognizes that it won't prevent it, but it's another therapy, a way to treat them, correct, in addition to anticoagulants or other medical treatments; correct?
A. It's -- correct. It's a therapy to prevent further harm from having that DVT.
Q. Okay. Thank you.
Now, we've talked about the benefit. The benefit is --
MS. HELM: And you can take that down, Scotty.
BY MS. HELM:
Q. -- is a treatment for this deadly disease of DVT or PE.
Are there also risks or complications with IVC filters?
A. Yes.
Q. The jury, for the last several days, has heard a lot about these risks. And are risks associated with medical devices inherent in every medical device?
A. In my experience, all the devices we've ever seen, or I've ever seen, have inherent risks in them.

Q. And, again, that's why you do this risk-benefit analysis?
A. Yes.
Q. Is that why --
A. The benefits must always outweigh the risks.
Q. Okay. And there are complications associated with IVC filters?
A. Correct.
Q. And is one of those complications migration or movement?
A. Correct.
Q. And is another complication tilt?
A. Yes. Greater than a certain degree.
Q. And is another complication penetration or perforation of the actual vena cava itself?
A. Yes.
Q. And is another complication that a part of the filter could fracture?
A. Yes.
Q. And based on your role as vice president of quality, do you also pay attention to medical literature?
A. Yes.
Q. Do you also pay attention to reports that are available about the -- about your competitors' filters?
A. Yes.
Q. And do you also have an opportunity to speak with physicians in the medical community who use IVC filters?

A. We do.
Q. Okay. And those complications that we just talked about -- migration, tilt, perforation, and fracture -- are those unique to Bard IVC filters?
A. No.
Q. Are those complications that are part of the risk of all retrievable IVC filters?
A. Yes, and they're recognized as such in literature.
Q. Thank you.

Okay. Does the quality department have a role in evaluating whether those risks are outweighed by the benefit of Bard's IVC filters?
A. Yes.
Q. It's a huge part of your role, isn't it?
A. Yes. In particular, in the product development area, of course.
Q. This jury has heard and seen parts of and different iterations of a document or various documents that have had the title DFMEA.

What does DFMEA stand for? What does the acronym stand for?
A. Design failure modes and effects analysis.
Q. Is that a tool used by engineers to evaluate their products?
A. It is. It dates back to, I want to say, the '50s in

military and aerospace, automotive.
Q. It's not unique to the medical device industry?
A. No.
Q. It's not unique to Bard?
A. No.
Q. And it's not unique to IVC filters?
A. No.
Q. Okay. Does the quality department -- does Bard use DFMEAs in their product development to evaluate their products?
A. Yes.
Q. Does Bard use DFMEAs beyond product development as a tool to help evaluate their products?
A. Yes. They're part of what's called a risk management system. And that's what we're seeing in accordance with international standards for risk management in medical devices.
Q. Okay. We're going to talk more about DFMEAs and hopefully look at part of one in a minute.

As vice president of quality, was part of your job also to be apprised of and to coordinate the analysis of complications reported about Bard IVC filters?
A. Yes.
Q. Okay. And as part of your role as vice president of quality, did you oversee the investigation of complication reports that came into the company about its retrievable IVC filters?

A. I did.
Q. And as vice president of quality for Bard, were you also responsible for tracking and trending the information about complications of Bard's IVC filters that were reported to the company?
A. Yes.
Q. And in that same role, were you also responsible for making sure that the company reported the adverse events and the complications that it -- about which it was notified to the FDA?
A. I was.
Q. In the medical device industry, are there standards for developing policies to evaluate products and to evaluate when a company needs to take actions for the products?
A. They're based on the risk management standards. International regulatory agencies have risk management standards, as I mentioned, that state that you must have a risk management system which evaluates the risks of products, continually evaluates those, and then rates those and then takes action when necessary.
Q. And does Bard follow a risk management standard to evaluate its products, compile its rates, and analyze them?
A. Yes.
Q. And what standard does Bard follow?
A. The external standard is ISO 14971, risk management for

medical devices.

Q. Let's talk about DFMEAs.

How is a DFMEA developed?

A. The DFMEAs start at the point of an idea of a product. So the format of it is identifying first potential failure modes of a device based on how it is used, what environment it's used in, what clinicians or patients might be using the device, and you list all those out. You have brainstorming sessions with not just quality, you have R&D, you have clinicians, you have regulatory folks.

And everyone gets that list together and then you develop it. So it starts right at the beginning of the development of a product. And as you learn more, you continually update it.

Q. So at the beginning of your product, you bring all of your brain trust together -- I apologize -- and you look at, okay, what are the possible risks, what are the possible failure modes?

A. Correct.

Q. And are those then documented in a form or in a -- in the DFMEA?

A. In a template. Those are all listed out. And then you begin to rate those for levels of severity. And then as you -- you may make up a mock-up of a new device, you learn more about it, you do testing, and you revise it during the development

process.
Q. So this DFMEA that evaluates failure modes and the potential risk or levels of severity of those failure modes, is that a static document that never changes?
And I want to just now talk about the development of a product. Is that a static document that never changes throughout the development of a product before a product is cleared for use in the market?
A. No. No. As -- it's expected that it's revised as you learn more information throughout the development. As you do more and more testing, have different test methods, ways of testing it, both in some instances in animals and clinical trials, in benchtop testing.
Q. And during this DFMEA process, this fluid process that's taking place, does Bard set thresholds or a bar or something by which it wants to internally evaluate its products?
A. So with the development of that DFMEA, there's severity and then there's the estimated occurrence. And by using literature, prior or similar product knowledge, clinicians' estimates of expectation, we begin to set estimates of occurrence of those types of failure modes. And so they're analyzed line by line by line.
Q. And how do you use those estimates of occurrence? How does Bard use those to evaluate the progress of the development or even to evaluate its products?

A. As part of development, when you have those estimates, there's a table. And the burden of the international standard is you must reduce those as low as reasonably possible. And by doing additional testing, by putting tighter controls in, by tweaking the design during development, you can get to levels that are understood to be reasonably as low as possible.
Q. And what is the benefit for setting thresholds as low as possible?
A. The idea is when you get to the end of the development, you're proving that your risks have been reduced as low as possible, not eliminated but as low as possible, and then the benefits are shared with FDA, with international regulators, and that's the burden of proof for approval.
Q. And if during the development of a product you find that a failure mode is exceeding your low threshold, what do you do?
A. You said during development?
Q. Yes.
A. You have to take additional action. So that may include, as I noted, tighter controls, modification of the final design, changes to communication to the customer, additional in-service training.
Q. And once a product is launched and a product's available in the community, do you still use DFMEAs in any way to evaluate how that product is performing in the community -- in the community?

A. Yes. Because as part of the complaint handling process, you're doing the investigation. And based on what is reported as the failure mode, we look back at the DFMEAs for that particular product and you look through the lines of that very thick document and see where that's been evaluated. And you're constantly evaluating it back to what was originally predicted in the DFMEA because you want to know is it performing at that level or not.

Q. And if you get information that shows that for a certain failure mode, the product is exceeding your low threshold, does that mean the product's unacceptable?

A. No.

Q. What does that mean?

A. It's set low for a reason, because if it was set high and you said that you had to take action after it being set high, then you wouldn't have to take action until a much higher rate. So by setting them low, it causes you to have like an early warning signal. You begin an investigation, and typically you look for commonalities of certain events; not just necessarily one event but groups of events that may have occurred.

Q. The jury's also heard some testimony about comparing thresholds or the predictions of DFMEAs for one product -- and I'll speak in examples -- example, for the Simon Nitinol filter versus the thresholds and the prediction for an Eclipse retrievable filter.

Is the purpose of a DFMEA to compare one product against another?

A. You can't, really, because those are set -- they have to be set by the product itself. They're inherent and tied to its design, its use, its intended uses. So just because they may have the same words that say migration or something else, those have to be set independently. And that's the burden of getting a device approved is establishing that.

MR. O'CONNOR: Excuse me, Your Honor. Objection. Move to strike that response in terms of "approved."

MS. HELM: Your Honor, I'll clear up --

THE COURT: Hold on just a minute.

Would you correct it in your question?

MS. HELM: Absolutely.

BY MS. HELM:

Q. Mr. Modra, you just talked about a product being approved. Did you misspeak?

A. Yeah, it's cleared.

Q. Okay. And just so we're clear, once Bard makes submissions to the FDA about a product, an IVC filter that it would like to place on the market, the FDA does not approve that product?

A. Correct.

Q. The FDA clears the product for sale?

A. That's correct.

Q. Thank you, Mr. Modra.

Can you draw any definitive conclusions about a product's performance in the market once it's been sold -- and we'll talk about IVC filters, once they've been implanted, based on the rates for adverse events -- which we're also going to talk about in a minute -- exceeding a DFMEA threshold?
A. Drawing their performance in the field just by --
Q. Just by exceeding the DFMEA threshold.
A. No.
Q. And why is that?
A. Because the DFMEA is originally a snapshot in time and then updated with that additional information. It has nothing to do with those performance in the field. It's an internal evaluation of those particular failure modes that are constantly being compared. So the numbers on one product DFMEA have nothing to do with another.
Q. Okay. Why do you compare the information that you're receiving about adverse events from the field to your predictions in the DFMEA, to the thresholds? Why do you do it?
A. Because during development we had put those controls in place intentionally to gather those estimates. That was part of our original submission.
And by comparing them, that gives us one indicator of is it operating the way we thought it was, at a rate -- at that lower rate. That doesn't necessarily mean it's violative, meaning in violation of the regulation. It's just our first

internal comparison to give us that early signal.
Q. Do FMEAs get updated periodically throughout the life of a product?
A. Yes. They're expected to be in a healthy risk management system. You actually have to demonstrate to investigators that come in from around the globe that you are actively monitoring them, that you're updating them, that you're gathering more information. It's expected to be updated periodically.
Q. And what happens to the old DFMEA when you update it, if you change a threshold based on information that you've learned?
A. The document is revised and archived.
Q. Okay. If Bard sees something in the adverse events that exceeds a DFMEA threshold or otherwise causes a concern, does Bard have a policy in place as to what to do?
A. It does.
Q. And what is that policy called?
A. It triggers an investigation, and then depending on if the investigation is part of a product that's been already distributed or has caused harm, it could lead to a remedial action, which is a complicated word for potential field action or a recall.
Q. And does Bard have policies in place on how to conduct an analysis or a -- for a remedial action?
A. Yes.

MS. HELM: Scott, would you please pull up 5565?

BY MS. HELM:

Q. Mr. Modra, can you see that?

A. Yes.

Q. And what is this document?

A. This is a remedial action standard.

Q. Is this an internal document created at Bard?

A. It is.

Q. And is this the document that governs the process you take if you're going to take a remedial action for a product?

A. It does.

Q. And is this a document that you are -- you're familiar with in your work as vice president of quality for BPV?

A. Yes.

Q. And was it created in the regular course of business for Bard or BPV?

A. Yes.

MS. HELM: Your Honor, at this time I move for the admission of Exhibit 5565.

MR. O'CONNOR: Well -- no objection.

THE COURT: Admitted.

(Exhibit No. 5565 admitted into evidence.)

MS. HELM: Scott, could you please turn to page 5565.18.

BY MS. HELM:

Q. Mr. Modra, do you see the page that's in front of you?

MS. HELM: I'm sorry, Your Honor. May I publish?

THE COURT: You may.

MS. HELM: The 14 Post-it notes are not doing it for us.

Scott, let's go back to the first page, since the jury didn't -- at my mistake, didn't have the opportunity to see it.

BY MS. HELM:

Q. And again, Mr. Modra, would you just explain very briefly what this document is now that the jury can see it and I'm not just talking about it in the abstract.

A. It's the policy for remedial actions.

Q. Okay.

A. The internal standard for remedial actions.

MS. HELM: Scott, would you now move forward to page 18, please.

BY MS. HELM:

Q. And, Mr. Modra, do you see on page 18 where it says a Hazard Risk Assessment Matrix?

A. Yes.

Q. Would you explain to the jury what that is, please.

A. It's a table that uses the four severity categories across the top, and then on the side, left side, is estimates of occurrence.

Q. And how are those used in evaluating a product?
A. For a particular event or issue, once we've done an investigation to determine that a group of events are similar, or have a particular cause, you have to make a decision what is the severity of that and what is the likelihood of it causing someone harm.
So you put those two numbers in this table and then you determine where it lands on the chart.
Q. Okay. Thank you.
We talked -- this jury's --
MS. HELM: Scott, you can take it down.
BY MS. HELM:
Q. The jury's heard about some analysis that a quality engineer named Natalie Wong did on a couple of G2 and G2X filters.
Do you know Ms. Wong?
A. I do.
Q. And is she a quality engineer at Bard?
A. I think now she's a quality engineering manager.
Q. And let me show you what is Exhibit 2248, please.
MS. HELM: And, Your Honor, this is in evidence. May I publish?
THE COURT: Yes, you may.
BY MS. HELM:
Q. This is an email with a PowerPoint attached to it called G2

Caudal Migration Update. And it's dated in March of 2006.

Do you see that?

A. I do.

Q. Okay. And as I told you, this email came from Ms. Wong. And at the time Ms. Wong prepared this email in 2006, was she a quality engineer at Bard?

A. She was.

Q. Okay. Do you recognize this document --

MS. HELM: Scott, would you flip to page 2, please.

BY MS. HELM:

Q. Do you recognize this document?

A. Yes. I've seen it before.

Q. Okay. And are you familiar with a document like this that are used as part of analysis of products at BPV?

A. I am.

Q. And based on your role as vice president of quality, did you become familiar with the analysis of the quality department done for products that were on the market while you were there, including the G2?

A. Yes.

Q. Have you had a chance to review this PowerPoint that's in Exhibit 2248?

A. I have.

Q. And is the analysis contained in Exhibit 2248 the type of analysis that your department routinely performs, or when you

were vice president, that your department routinely performed on IVC filters?

A. Yes.

MS. HELM: So if you would turn to Slide 1, please, Scott.

BY MS. HELM:

Q. It appears that she did a quick chronology of the G2 filter, and she's addressing caudal migrations; is that right?

We can go back to page 1.

A. Yeah. I see that.

Q. Okay.

MS. HELM: And, Scott, if you would turn to page 20.

BY MS. HELM:

Q. What is this -- what is this slide explaining on page 20?

MR. O'CONNOR: Objection, Your Honor. Lack of foundation. This is -- may I ask the witness a quick voir dire question? I just want clarification when he came to Bard.

THE COURT: Would you reask that question -- or would you lay that foundation, please, Ms. Helm?

MS. HELM: Sure.

BY MS. HELM:

Q. Mr. Modra, you were not at BPV in 2006, were you?

A. I wasn't.

Q. As part of your role as vice president of quality for BPV, were you responsible for understanding the analysis of products

that were on the market when you came to Bard in 2011?
A. It was.
Q. And was -- and as part of your responsibility as vice president of quality, were you responsible to know the history and the analysis of products such as the G2, the G2X, and the Eclipse?
A. I was.
Q. And is this the type of document you would review to analyze and understand the history of those products?
A. Yes.
Q. Would you please explain to the jury what page 20 -- what it is and what it says.
MR. O'CONNOR: Still objection, lack of foundation as to this document and under what circumstances it was created.
THE COURT: Let's talk about this for a minute, counsel.
If you want to stand up, ladies and gentlemen, feel free.
(At sidebar on the record.)
THE COURT: Mr. O'Connor, I want to make sure I understand what your objection is.
MR. O'CONNOR: Well, they're bringing in a witness here who's not been designated as an expert now, who came into Bard in 2011, to now somehow interpret a document that was done in real time back in 2006. I don't think he's qualified, and I

don't think it's appropriate for them to bring in --

THE COURT: Well, is it a Rule 602 objection?

MR. O'CONNOR: Yes, 602 and just plain lack of foundation.

THE COURT: Well, there is no plain lack of foundation. It has to be based on a rule. It's either lack of knowledge, 602, lack of authentication, which I don't think is relevant here.

MR. O'CONNOR: No.

THE COURT: So it's a 602 problem?

MR. O'CONNOR: It would be a 602 problem, and I think it's also a 702 problem.

THE COURT: You think it's expert opinion?

MR. O'CONNOR: I think that's where they're going with him, yes.

THE COURT: All right. What's your response, Ms. Helm?

MS. HELM: Your Honor, he's testified that he was responsible for knowing the history of the products, including the G2, the G2X, and the Eclipse; that this is a document that he had reviewed; that he's familiar with it; and as vice president of quality, he was responsible for the products that were still around when he came on.

I think I've laid the foundation that he -- this is the type of document he reviewed. He testified that he did.

Also, he -- as vice president of quality, he has clearly stated that he's familiar with the DFMEA process and the investigation process in the filters, and that's what Ms. Wong was doing at the time. She was analyzing documents. She's in the very department that he is responsible for. And so I believe he can explain to the jury the contents of that page and what they mean.

THE COURT: Did you want to say anything else?

MR. O'CONNOR: Well, he testified that these change over the years, that they aren't static, and we already heard from Natalie Wong who created this document, who was there at the time and knew the circumstances underlying what was going on at Bard.

THE COURT: All right. Well, it's clear to me from his testimony that he understands the DFMEA process. He has personal knowledge of it and how it was applied within Bard. I think he can testify from his personal knowledge about that, including what his personal knowledge would tell him this DFMEA analysis means.

You absolutely can bring out on cross-examination that he wasn't here at the time. He didn't receive it at the time. He doesn't know the con -- the actual context, but it's clear to me he has personal knowledge of the process and can testify about that and what he thinks it means in light of that process, and you can cross-examine.

MR. O'CONNOR: Well --

THE COURT: So I'm going to overrule the foundation objection.

MR. O'CONNOR: My other concern is bringing these witnesses in who probably had -- this was -- who are looking at these things for purposes of litigation and trying to use them as experts in this case when they haven't been disclosed.

THE COURT: I don't think this is expert testimony. Expert testimony, as you know -- I mean, if he's giving an opinion, it would be under 701, because he's not an expert. And he cannot do that if it is based on expert qualifications under Rule 702.

I don't think that's what he's doing. He's testifying from his experience as an employee of Bard rather than as an expert in some specialized field. But you can cross-examine on all of those foundation issues.

MR. O'CONNOR: Thank you.

MS. HELM: Your Honor --

THE COURT: Hold on just a minute.

MS. HELM: I'm just asking, is it okay if I go to counsel table and get some water?

THE COURT: Of course, yeah.

MS. HELM: Okay. Thank you.

(End of discussion at sidebar.)

THE COURT: Thanks, ladies and gentlemen.

BY MS. HELM:

Q. Mr. Modra, we're back on Ms. Wong's analysis on -- and her G2 Caudal Threshold on page 20.

Let me back up for just a minute and clarify something. You were not at Bard in 2006; correct?

A. At Bard, but not at BPV.

Q. Okay. And so when Ms. Wong prepared this, it didn't get distributed to you?

A. No.

Q. But it's the type of analysis that occurs on a regular basis in the quality department at BPV; correct?

A. Yes.

Q. And as vice president, when you came on board, you were responsible for understanding what had gone on with the products, how they were analyzed, and moving that process forward, were you not?

A. I was. I spent time with my predecessor, who had -- Ms. Gin Schulz, who had been there at the time.

MS. HELM: And, Scotty, can we go back to page 1, please.

BY MS. HELM:

Q. In fact, this email is addressed to Ms. Schulz; is that right?

A. Yeah, it is.

Q. Okay. And she was your predecessor as vice president of

quality at BPV?
A. She was.
Q. And as part of your transition or coming over to that role, you met with her and had to learn some of the history of the products you were responsible for; is that right?
A. That's correct.
Q. Okay. And in your 20-plus years of working in the medical device industry, how many of those have involved with -- working with DFMEAs?
A. At least the last 18.
Q. Okay. Thank you.

Let's go back to page 20, please.

Would you explain to the jury what this G2 Caudal Threshold, what this first table at the top is depicting?
A. From the column headings, I can see that the FDA code is reflected and then there's a typing of those failure modes. And that failure mode involves four different types of different severities, and you can see that in the Severity column sort of in the middle of the table. And it reflects the four different time periods, the current complaint rate related to those types of migrations per the DFMEA.
Q. Okay. Is it your understanding that Ms. Wong was looking at returns -- information that was provided to Bard about IVC filters implanted in patients; right?
A. Correct.

MR. O'CONNOR: Objection. Lack of foundation on what Ms. Wong was thinking or doing at this time.

THE COURT: Sustained.

BY MS. HELM:

Q. Mr. Modra, when you prepare a document like this in the quality department at BPV, where do you get that, the information to use?

A. We get it from complaints that we have input into our system.

Q. Okay. And when you get those complaints, can you do an analysis of those complaints compared to the thresholds you predicted for the DFMEA?

A. We can because the complaint rate -- the complaint investigation itself uses the code as noted here, the FDA code in its summary. So it's easy to pull those out and do the comparison.

Q. And what is the FDA code that Ms. Wong recorded on page 20 of Exhibit 2248?

A. It's 1395, known as migration.

Q. Okay. And is that a code you're familiar with?

A. Yes.

Q. And does it refer to caudal migration?

A. Any migrations.

Q. Okay. And when you get over to the fourth column, the column that says Complaint Rate -- do you see where I am?

A. I do.
Q. What are those?
A. Those are the reported events that we have taken in, divided by the number of units distributed --
Q. Let's --
A. -- for that particular failure mode.
Q. Okay. Let's stop right there to make sure we're all clear.
For some period of time, you know how many IVC filters were distributed or sold?
A. Correct.
Q. And for that same period of time, can you determine how many adverse events you've received against those filters that were sold?
A. Yes. You query a certain time period, and then we have the sales figures for those product codes and the reported events.
Q. Okay. So let's go back.
Number 1 -- or the column that says Number of Complaints, do you see where I am?
A. Yes.
Q. That's the -- is that the number of adverse events reported?
A. Yes.
Q. And is Column No. 2, the Total Units Sold, is that what we're talking about, the number of units that were sold?
A. That's correct. That's the denominator.

Q. And is Column No. 3 the rate that was calculated using the number of complaints --

MR. O'CONNOR: Objection to the leading, Your Honor.

BY MS. HELM:

Q. What is Column No. 3?

THE COURT: Sustained.

BY MS. HELM:

Q. What is the Complaint Rate column? How do you calculate that rate?

A. It's the number of complaints divided by number of units sold times 100 percent.

Q. And there are four different categories of migrations in your DFMEA. And did Ms. Wong record rates for migration for those 8,924 units sold in the Complaint Rate column?

A. She did.

Q. And what were those rates for -- starting with Type I down to Type IV?

A. .03 percent; .02 percent; .09 percent; and 0.

Q. Okay. On the far right -- and what was the overall complaint rate for migration against those 8,924 filters?

A. .15 percent.

Q. And over on the right side, there's a column that says Quad Level.

Do you see that?

A. I do.

Q. And what is a quad level?
A. In the risk management standard and the DFMEA procedure, there are quadrants. And you can see a depiction of that actually below that column, four quadrants: The lowest, Quad 1 being broadly acceptable; Quads 2, 3, and 4 increasing severity or hazard.
Q. Okay. You see the box that says Unacceptable Risk Per FMEA? Do you see where I am?
A. I do.
Q. Would you explain to the jury your understanding of what that means.
A. Per this table, whenever you have a Quad Level 3, it would be listed as unacceptable but in that -- the procedure says you have to do something about it. You have to take investigation if it's post-market, or you have to consider other controls in place if it's in the development area.
Q. And the two Quad Level 3s that she says are unacceptable, would you tell the jury what the complaint rate was for each of those quad levels?
A. Type III was .09 percent and Type IV was 0.
Q. How can a .0 -- how can no event be unacceptable per the FMEA?
A. And that can be sometimes confusing, because if you look on the table on the bottom right-hand side, severity is a 5. So if you have a type of a failure mode that's a severity 5, you

can see there's no way to not have at least a Quadrant 4 or a Quadrant 3 result.

And that would be, in risk management, considered residual risk or the inherent risks of a device. You can't lower it below that for certain severities. So as part of the final write-up for risk versus benefit, that's called out as one of the risks.

Q. When it says, "unacceptable per FMEA," in your experience as vice president of quality for BPV, does that mean that there's something wrong with the product?

A. It's the early signal trigger that I mentioned before. It's something that we have to take a look at because it's different than what we predicted. So that's why we started an investigation in this area.

Q. Okay. Are you familiar with an investigation that Bard did relating to caudal migration in 2006/2007?

A. Yes.

Q. Okay. And was that -- what was the complaint rate -- what was the rate for migration that triggered -- the complaint rate that triggered that investigation?

A. It was a .09 percent.

Q. And what investigation did Bard undertake in response to a complaint rate of .09 percent for caudal migration?

A. They did -- we did an analysis at the time of any potential manufacturing causes of this. I know that there was a

physician panel convened, I believe, probably in my hometown -- it was Chicago at the time -- to ask and get more feedback on is this an acceptable rate, is this of concern.

Q. So based on the -- and what Ms. Wong analyzed, was that a snapshot in time?

A. Yeah. It's across a certain time period. I can't recollect which time period it was.

Q. And we'll just refer to it as a snapshot since we don't have the time period.

So based on this snapshot in time and this complaint rate of .09 percent, Bard initiated an investigation into the product?

MR. O'CONNOR: Objection. Leading.

BY MS. HELM:

Q. Did Bard --

THE COURT: Excuse me.

Sustained.

BY MS. HELM:

Q. Did Bard initiate an investigation into the product?

A. Yes.

Q. And is that the investigation you just explained to the jury?

A. It was.

Q. Would the development engineers have been involved in that investigation also?

A. Yes.
Q. And what would their role have been?
A. Development engineers are the ones that during the initial development of the product have gone out and talked to clinicians, gotten their opinions on what they're concerned about, how they'd like a device designed. So they're undoubtedly involved in that analysis.
Q. Thank you.
MS. HELM: Scott, will you take that down, and would you pull up Exhibit 443, please?
Mr. Modra, the jury's heard about --
I'm sorry, Your Honor. This is admitted. May I publish?
THE COURT: Yes, you may.
MS. HELM: Your Honor, the jury's heard about another document prepared by Ms. Wong --
THE COURT: Are you asking me this question?
MS. HELM: I'm sorry. As soon as it came out of my mouth, I realized I misspoke. I apologize.
Let me try that again.
BY MS. HELM:
Q. Mr. Modra, the jury has heard about another document created by Ms. Wong, which is a G2 and G2X fracture analysis.
Are you familiar with this document?
A. I am.

Q. And, again, did Ms. Wong work in the quality department?
A. Yes.
Q. Is that the department you were responsible for?
A. Yes.
Q. And when you joined Bard, or BPV, did you take the opportunity to look back at analysis that had been done for the products that you were responsible for at BPV?
A. I did.
Q. Okay. And is this the type of analysis and document that you reviewed in your role as vice president of quality for BPV?
A. It is.
Q. Are you familiar with this document?
A. Yes.
Q. Is this a final version?
A. It says "Draft," so I would say no.
Q. Okay. And based on your review of this document, what do you understand that it was analyzing?
MR. O'CONNOR: Objection. 601 again. Lack of foundation.
THE COURT: Overruled.
THE WITNESS: The product, G2 and G2X fractures.
BY MS. HELM:
Q. And as with the prior --
MS. HELM: Scott, can you turn to page 2, please?

BY MS. HELM:
Q. Can you explain to the jury what page 2 shows.
A. It's top-level summary. It explains first the reporting date, so the date of which she's taken the data from; it includes the product codes or what we would refer to as the product codes for each of the different types or kits of filters; and then it gives a summary of the key elements of units distributed, complaints related to fractures.
Q. Let's go back.
In this document, what is the reporting range date that Ms. Wong was analyzing?
A. Looks like July 1st, 2005, through November 30th, 2008.
Q. And then you have Product Codes, and does every G2 or G2X, whether it's going to be implanted through someone's neck or through someone's thigh, get a product code?
A. It does. F would be femoral, and J is jugular. It's the placement location or insertion location.
Q. And in -- as part of her analysis, did Ms. Wong include the number of G2 and G2X IVC filters that were distributed between July 1, 2005, and November 30, 2008?
A. She did.
Q. And what is that number?
A. 100,826.
Q. And as part of her analysis, did Ms. Wong calculate the rate of fractures in that 100,826 G2 and G2X filters based on

information provided to the company?
A. She did.
Q. And what was that rate of fracture for G2 and G2X filters for that approximately three-year-plus time period?
A. .06 percent.
Q. Before we leave that page, Mr. Modra, that .06 percent is based on -- it was 56 reports of fracture? Was it 56 reports of fracture?
A. Yes.
Q. Of those 56 reports of fracture, how many of those did Bard report to the FDA?
A. 56.
Q. And if you take 56 and divide it by 100,826 -- and I'm asking you to do math in your head -- but that comes out to .06?
A. I can't do it in my head, but based on this, it would be .06.
Q. Okay. So in other words, for this three-plus-year time period for G2 and G2X fractures, there were less than six reported fractures for every 10,000 filters placed?
MR. O'CONNOR: Objection. Leading.
BY MS. HELM:
Q. Is my math --
THE COURT: Sustained.

BY MS. HELM:
Q. In other words, were there less than six reported fractures for every 10,000 filters sold?
A. Yes.
MS. HELM: Scott, would you please turn to page 6.
BY MS. HELM:
Q. Mr. Modra, based on this, are you able to tell the jury, of those 56 fractures, how many of the patients, based on the information that was reported to Bard, were asymptomatic; in other words, they had no complications from the fracture?
A. Yes.
Q. And what is that number?
A. 43.
Q. This is titled a "Fracture Analysis." How often does Bard do this type of fracture analysis?
A. Monthly.
Q. And why do this type of analysis?
A. Because we want to make sure that we're always on top of any potential changes that have occurred.
MS. HELM: And, Scott, would you please turn to page 18.
BY MS. HELM:
Q. Mr. Modra, are you familiar with this page?
A. I am.
Q. And is this page -- would you explain to the ladies and

gentlemen of the jury what this page is?
A. This, down the left-hand side, includes from the fracture reports the correlative other items that have occurred. Meaning, of the fractures, there's two different types; Type A, Type B. There's the type of fracture; was it a limb detachment, arm, hook, or leg. The number of days to discovery. Asymptomatic, symptomatic, and so on with the other complications included.
Q. So this is -- is this a further analysis of those 56 reports of fracture out of the over 100,000-plus filters distributed?
A. It is.
Q. And would you explain to the jury -- and we're going to work with the G2. And back on page 2, I believe you said that the rate of fracture for that approximately hundred thousand-plus filters was .06 percent?
A. Correct.
Q. Okay. So in our mind, if we put .06 percent next to G2, that's the rate that is being -- is that the rate that's being further analyzed here?
A. Yes.
Q. And if you would go down, do you see where it says Caudal Migration, 14 percent?
A. I do.
Q. Would you explain to the jury what that means.

A. What's depicted there is 14 percent of the .06 percent reported events, or 14 percent of 56, is what is -- also had caudal migration indicated with it.
Q. So 14 percent of the 6 percent return rate had -- of those fractures had a caudal migration?
A. Yeah. 14 percent of the .06.
Q. Okay. And if you wanted to get the rate of those 100,000 filters that had both a fracture and a caudal migration, how would you calculate that rate?
A. You'd multiply those two together.
Q. So you would multiply .06 by .14, 14 percent?
A. Correct.
Q. And I'm not asking you to do it in your head, but if you do .06 by .14, do you agree that it comes out as something .008 or smaller?

MR. O'CONNOR: Objection. Leading again.

THE COURT: Sustained.

BY MS. HELM:
Q. If you do that math in your head, what number do you come up with?
A. It would have to be significantly smaller, less than a quarter of .06 percent.
Q. Okay. And then the same thing, the next column down, you see where it says Tilt?
A. Yes.

Q. And, again, is that -- what does that depict?
A. That is saying of the reported fractures, what percent also noted tilt.
Q. Okay. And, again, to calculate the percentage of fractures that had both fracture and tilt, you would have to calculate the number of what is 39 percent of .06?
A. That's correct.
MR. O'CONNOR: Leading.
BY MS. HELM:
Q. Would you have to --
THE COURT: Hold on.
Sustained.
BY MS. HELM:
Q. How would you calculate that number?
A. .06 times .39 percent.
Q. Okay. And would that be a number smaller than .06?
MR. O'CONNOR: Objection. Leading.
THE COURT: Overruled.
THE WITNESS: It would be -- yes. It would be less than half of .06, maybe .028-ish.
BY MS. HELM:
Q. And, finally, the column that says Perforation, would you explain to the jury what that column is.
A. Similarly, it's the percent of those fracture events that also reported perforation.

Q. And, again, if you were going to determine the rate of the 100,000-plus G2 and G2X filters that had both perforation and fracture, how would you calculate that rate?
A. .06 times .36.
Q. And roughly, that's a number much -- is that a number smaller than .06?
A. Again, roughly less than half, so somewhere around less than .028.
Q. Is Ms. Wong's analysis in looking at filters, G2 and G2X filters from 2005 to 2008, the type of analysis that Bard performs on a regular basis?
A. Yes.
Q. And are the -- does Bard look at more than just whether it was a fracture?
A. Yes.
Q. And is that what Ms. Wong did here?
A. Yes.
Q. On the right-hand side, next to G2, it says RNF. Do you know what that stands for?
A. Yes.
Q. And what is that?
A. Recovery Nitinol filter.
Q. So Ms. Wong -- did Ms. Wong compare the G2 to the Recovery Nitinol filter?
A. She also put those next to -- she did a similar analysis

for Recovery.
Q. Okay. And do you know if her time period for the Recovery was the same as her time period for the G2?
A. From the earlier page, in order for it to be a similar comparison, it should be the same time period. I don't know exactly for sure in this instance.
Q. And you acknowledge that in some instances, the G2 -- the IVC filters with fractures for the G2 had higher rates of either migration, tilt, or perforation than the Recovery filter; correct? The percentages are higher?
A. They are in some co-complications.
Q. Okay. Does that cause you concern?
A. Not necessarily. We have to look at the device as a whole, how it's performing and its benefits. There may -- there's other benefits to G2 versus Recovery, similar with other devices.
Q. And do rates that are a percentage of .06 cause you concern?
A. Percent --
MR. O'CONNOR: Object to the form. Objection, Your Honor. That calls for an opinion.
THE COURT: Overruled.
THE WITNESS: Percentages of any reported events would cause me concern in that I want to have as low as possible. But in the risk-benefit comparison, these rates are extremely,

extremely small.

MS. HELM: Thank you.

You can take it down, Scott.

BY MS. HELM:

Q. I'm going to shift gears a little bit.

As part of your role as vice president of quality, were you responsible for the development of policies and procedures for the department?

A. Yes.

Q. Did you have responsibility to also be familiar with past practices and how things were done before you got there? We talked about that a little bit.

A. Yes.

Q. Okay. We've talked about rates. We've heard about rates. You and I just explained the rates that Ms. Wong had calculated.

Let's step back a minute. Would you please tell the jury again, when we're talking about a rate of a condition for a filter -- and we'll use fracture -- how is that rate calculated?

A. From the reported events and any other events that we proactively find in literature, we put those into our complaint database. From that, a code is assigned to it. If it's mentioned as fracture related, that code gets assigned to that file.

And then we sort out those for -- across a time period. So the rate is calculated based on whatever the time period taken and the count of each one of those records, divided by the correlative sales figures for that same time period.

Q. One of your sources is -- and the jury's heard you speak previously about complaints. One of your sources of information to calculate your rates is what are called complaint files. Is that right?

A. That's correct.

Q. Okay. And does Bard have policies and procedures that govern how complaints are addressed when they are reported to the company?

A. Yes. From the time we're first made aware of it through complete investigation and closure.

MS. HELM: Scott, would you please pull up 7961.

BY MS. HELM:

Q. Mr. Modra, are you familiar with this document?

A. I am.

Q. And what is this?

A. It's the internal standard for product complaint handling.

Q. And will you -- while you were in your role as vice president of quality, is this a document that you were responsible for implementing and making sure it was followed?

A. Yes, I was.

Q. And is this a document that was created and maintained in the ordinary course of business at Bard?
A. Yes.
Q. And if you look at this, is this a document that was in place when you joined Bard?
A. BPV?
Q. Okay. Yes.
A. Yes.
MS. HELM: Your Honor, at this time, I move to admit Exhibit 7961.
MR. O'CONNOR: No objection.
THE COURT: Admitted.
(Exhibit No. 7961 admitted into evidence.)
MS. HELM: May I publish, Your Honor?
THE COURT: You may.
BY MS. HELM:
Q. Mr. Modra, what is Bard's goal for processing incoming complaints?
A. Well, one, to completely analyze all complaints, conduct tracking and trending, and report those events which under regulation are required to be reported.
Q. What departments at Bard are responsible for receiving complaints?
A. All departments are responsible for being aware of when something might be a complaint and report it to the field

assurance department, which is the department under quality that I oversaw.

Q. And what department analyzes or investigates the complaint?

A. Field assurance.

Q. How do complaints get to field assurance? What are the sources of those complaints?

A. They can be through a telephone call, an email. We have an 800 number on all the products. They can be reported through a sales rep. Through email, again, through a call. We have people manning the phones all the time.

And then we also have another group called MS and S that handles customer questions about products -- is something so long, is something of this size, et cetera -- and orders. If they have any indication that that is a customer complaint, they -- and even if it's -- they suspect it might be, they also transfer those to our department and we take it down as a complaint.

Q. Is public literature a source of communication about adverse events or complaints with Bard's filters?

A. It is. Published literature, articles, yes.

Q. And is that something that field assurance also records and calculates?

A. They do. If -- we get standard emails from across the industry. If we see published articles, any one of us will forward that to field assurance as well. They do the same

proactive review.
Q. If a sales rep -- and we've heard from a sales rep and a sales manager. If a sales rep is having a conversation with a doctor and the doctor mentions an adverse event with any product, but particularly an IVC filter, would that be reported?
A. It would be.
Q. And are sales reps trained to report things that they hear when they're communicating with the medical community?
A. They are. I've stood up in front of them and trained them.
Q. That was part of your role, was to train them?
A. It was.
Q. Okay. So from whatever source, once field assurance receives a complaint, are there other -- are there circumstances where other departments in Bard will be involved in analyzing or investigating that complaint?
A. There are. We take down, again, all the information we can get, make multiple attempts to get that information, and then also try to get the device back. That's very helpful. If there's pictures, medical records, narrative, clinician notes.
And we put that all in the file. And we have to be expeditious about it, but we have engineers who also take that device, if we do get it back, to a lab. We do measurements on it. We take pictures. We do other tests on it, and that's where we get research and development involved.

They'll -- if there's something particularly of interest, something unique, something -- we think they want to see, we'll get them involved, get their opinion on it as well.

Q. Okay. As far as keeping track of adverse events that come in through all these sources, in addition to the investigation, you're responsible to keep track of the numbers of these events?

Are you responsible for keeping track of the numbers of these events?

A. Yes. They're all in a database.

Q. And are you responsible for categorizing or coding the events; in other words, so that there's a way to know if it's a fracture or a migration?

A. Yes.

Q. Okay.

THE COURT: We're going to take a break at this point, Ms. Helm. We will resume at 2:45.

Ladies and gentlemen, we'll excuse you.

(Recess taken, 2:29 p.m. to 2:44 p.m.)

THE COURT: You may continue, Ms. Helm.

MS. HELM: Thank you, Your Honor.

BY MS. HELM:

Q. Mr. Modra, before the break we were talking about how Bard records the information it receives about adverse events.

Do you recall that?

A. I do.
Q. Okay. Does the FDA have a set of codes that Bard is required to use to classify these adverse events or complaints?
A. They do.
Q. And are those codes by the failure modes? For example, the failure modes we've talked about; fracture, migration, tilt, perforation?
A. They are.
Q. And does Bard use those FDA codes for its internal recording, tracking, and trending of complaints and adverse events?
A. We do for all complaints.
Q. And if a complainant, for example -- if you get a report in, for example, of a fracture, how is that categorized or coded for tracking and trending purposes? What is the FDA code for that or language for that?
A. I can't remember the exact code.
Q. I don't need the number. How is it described? Is it described as a detachment?
A. Detachment. That's the word I always forget.
Q. Thank you.

What is the purpose -- you get a complaint. You get information. What is the purpose of that complaint investigation that the field assurance department does?
A. To learn about the customer experience. To learn about

what has occurred or what has happened to the patient, learn about has the device performed as it should. And then get a root cause investigation to determine, if there's a failure that has occurred, is it manufacturing related, is it environmental, patient, design, physician; anything that we can determine from the investigation.

Q. Are there many factors or situations that can cause an event to be reported as an adverse event?

A. Yes. I mean, it can range anything from if a doctor said that it did not perform as it expected, maybe there was something odd about the way the device performed, that would be a complaint. If -- even if they said they really don't prefer, for instance, the color of the device, we record that as a complaint. From those all the way to, obviously, any injuries, failures, physical failures of the devices, or up to including serious injury and death.

Q. When you were here on Tuesday, Mr. O'Connor talked to you about three individual complaint files that had been created based on information reported to Bard.

Do you recall that?

A. I do.

Q. Okay. And do you recall Mr. O'Connor asked you about whether Bard did a root cause analysis for those three complaints?

A. I recall that.

Q. Okay. What sort of limitations does Bard have in determining the root cause analysis for an event that's reported to the company?

A. One, we're limited by, even though we make multiple attempts to get as much information as we can, sometimes people are not willing or don't know what actually occurred. So they give us what they can or what they are allowed to.

Even though we write all that information down, we also request the device itself. Oftentimes we don't get the device back. People will either discard it or keep it for their own analysis. We also try to get medical records. Obviously we protect confidentiality, but they're sometimes not willing to give us medical records.

So it does make it difficult, at times, to be able to come to any sort of root cause when you're working with very limited information.

Q. But is it Bard's policy to do an investigation and root cause analysis for -- as much as possible for every complaint it receives?

A. That's our charge. Absolutely.

Q. Has that been Bard's policy the entire time that you've worked at Bard?

A. Yes.

Q. And are you often able to get the filter back?

A. Not very often. A lot of times, again, the event, you

know, predominantly being asymptomatic, sometimes it is noticed upon retrieval, so those devices are often discarded. I don't know offhand what percentage we get back, but it's not very often.

Q. So even if Bard is not able to obtain the filter or complete information to do a full root cause analysis, does Bard record and track and trend the adverse events?

A. We do, based on whatever is reported to us. So depending on what device they say it is, we record that. But we can't necessarily verify it because we haven't seen the device.

So we record it as is. We will track and trend those based on whatever they say the experience has been. And then it's also helpful to have the product code and the lot number, because if we have that, then we always go back and look at manufacturing records to see if there's -- you know, based on what failure mode they said, is there something in manufacturing that would have caused us to say that that's correlative.

Q. Even if you get a filter back for inspection, are there challenges in determining what caused a filter to fracture, for example?

A. Yes. I mean, it's been a device that's been implanted in a person for some time, typically. During removal it can be twisted, bent, any number of things.

So we get those back. We do measurement analysis on

them. We'll do high-powered inspection, video inspection, a visual inspection on them to look for defects.

And then we document all that as part of the record.

Q. Do you recall, when Mr. O'Connor was questioning you, he asked you why Bard did not do an FEA analysis for filters that it received in part of the field assurance complaint gathering.

Do you recall that?

A. I do.

Q. Let's stop for a minute. We've had DFMEA, and now we have another acronym.

And for those of us who are not engineers, what is FEA?

A. It's referred to as finite element analysis. And in the past I've had cause to do those in -- typically in design side, because they involve properties of a material, dimensions of a material, and then forces placed on those properties to see how they'll bend or what forces are involved. And it's evolved nowadays, too, even much more than when I did them originally, but it's typically done during design.

Q. Based on --

I'm sorry. Go ahead.

A. The reason why I had responded before like that is we wouldn't do that on a device that's already had itself subjected to something in a human being when it's meant to test the original properties. We have the review of manufacturing

documents, which show that those properties are controlled from the source, from the supplier, and then through the annealing process and manufacturing.

Q. Have you had an opportunity to go back and look at the three complaint files that Mr. O'Connor spoke with you about on Tuesday?

A. I have generally, yeah.

Q. And based on your review of those complaint files, did Bard do as much of a root cause analysis as was possible for each of those complaints?

A. Yes, I would say we did. I think one was not returned to us because it remained implanted in the patient, I think. The other one, we didn't get the device back; and the third, I can't remember the circumstances. But we didn't get as much information as we could, but we still attempted to do a root cause.

Q. And, again, when a complaint is investigated, is it Bard's policy, if the filter is available, to attempt to obtain the filter for an analysis?

A. Always. We always ask for it back. We make multiple attempts to try and get it back.

Q. And is it Bard's policy when it's evaluating a complaint made to the company to obtain as much information as possible?

A. It is.

Q. Now we've talked about thresholds. We've talked about how

you get information that you use for rates. We've talked about sales numbers to use for rates.

Does Bard also have a reporting requirement to the FDA to report adverse events?

A. We do.

Q. Okay. And how does that work? How often? What does Bard have to report?

A. According to the regulations, FDA says they want to know about things that have had a reported death, a serious injury, or things that are called malfunctions that could reasonably or have in the past shown to contribute to a serious injury to a patient.

So those are a subset of the total complaints that we receive.

Q. Does Bard have policies and procedures in place about when to report information to the FDA?

A. We do.

MS. HELM: Scott, would you please pull up 7962, please?

BY MS. HELM:

Q. Mr. Modra, can you see that?

A. I can.

Q. And what is this document?

A. It's the standard for medical device reporting within Bard.

Q. And are you familiar with this document?

A. Very.
Q. And as vice president of quality, was it your responsibility to make sure that your department was following the procedures in this department -- in this document in reporting information to the FDA?
A. It was.
Q. And is this document created and maintained in the regular course of business of Bard?
A. It is.
MS. HELM: Your Honor, at this time I move to admit Exhibit 7962.
MR. O'CONNOR: No objection.
THE COURT: Admitted.
(Exhibit No. 7962 admitted into evidence.)
MS. HELM: May I publish, Your Honor?
THE COURT: Yes.
BY MS. HELM:
Q. Why did Bard create this document?
A. To set the internal standard for the requirements of reporting adverse events, known as MDRs, to the FDA.
Q. Does Bard report to the FDA only those complaints that occurred in the United States?
A. No. If we hear about events of products that are sold outside the U.S. for devices that are similar in the U.S., we have to report that as well.

Q. Okay. In making the decision about whether an event should be reported to the FDA, how many Bard employees look at it? How many Bard employees are involved?
A. Typically, a minimum of three.
Q. Three?
A. Three.
Q. And what are their roles or functions?
A. One, there would be the field assurance specialist. That is, taking the narrative. They review their information, that they've documented all the back-and-forth with the reportee. Then there will be a field assurance manager and then a quality manager who does a check on the files themselves.
Q. If Bard is unsure whether information provided rises to the level that it should be reported to the FDA, what does Bard do?
A. If you can't rule out reporting the record, then you have to report it.
Q. And this reporting to the FDA, there's a form. Does it have an acronym?
A. The 3500 A is the form number.
Q. And is it also sometimes referred to as medical device reporting or an MDR?
A. Yes.
Q. So we're swimming in acronyms here, but -- so a complaint comes in. Is the complaint then investigated?
A. That's correct.

Q. And internally, does Bard then record the information so it can keep track of all of the adverse events that are reported to it?
A. That's correct.
Q. And then does Bard also, subject to the regulations and its policy, report certain information to the FDA?
A. Yes.
Q. Okay. And once Bard learns of an adverse event, how quickly does Bard have to report that information to the FDA for either a serious injury or a malfunction of the product?
A. 30 days.
Q. If Bard -- you report it in 30 days, and if your investigation takes longer because you're trying to get additional medical records or the filter or things like that, what does Bard do to supplement the information provided to the FDA?
A. You have to make the initial filing within 30 days, so you get what information you can and then you file that based on the information available.

Then if we receive information at some later time, we amend the complaint file, and then you have to file what's called a supplement. And they have a little check box on the form that says this is the second or the third or the additional supplemental materials.

Q. Now, we talked about the four different complications that

the jury's heard about: fracture, tilt, perforation, and migration.

With regard to IVC filters, does Bard report each and every incident of fracture it learns about to the FDA?

A. We do.

Q. With regard to migration, does Bard report each and every report of migration of its IVC filters that it learns about to the FDA?

A. We do.

Q. I'm going to ask the same question about perforation. With regard to perforation, does Bard report each and every instance of perforation of its IVC filters that it learns about to the FDA?

A. We do.

Q. And finally, with tilt, does Bard report every instance of tilt that it learns about regarding its IVC filters to the FDA?

A. We do.

Q. You've mentioned a few minutes ago about tracking complaint rates, these complaint rates. That's not a static system, is it? It's not a static -- that's something -- rates change over time?

A. Yes.

Q. Okay. And we looked at, for example, a couple of snapshots of time that Ms. Wong analyzed previously, didn't we?

A. That's correct.

Q. Okay. How often does Bard track the rates of returns for adverse events for its IVC filters?
A. Well, with each investigation, there's a form that's run. It's a statistical analysis that includes looking at all of those reported events for the same failure modes across the previous two years.
Q. And --
A. So it's always a rolling -- with every record, it's reported.
Q. And do you do this month -- do you look at it monthly? Weekly? How often do you look at it?
A. It's included on each complaint record, and then we report to our management review every month.
Q. So does -- each month, does the quality department prepare a report of some type that includes the rates of adverse events for the IVC filters? And I'm going to stick to those four categories that we've talked about.
A. Yeah. There are very extensive reports every month.
Q. Okay. What's the purpose of tracking those adverse events -- and you've talked about trending. We'll talk about it in a minute.
What's the purpose of tracking about them internally -- tracking them internally?
A. Monitoring them. I mean, keeping an eye on our products. We want to know how they're performing. We want to know what

experiences the patients are having every month. So that's why we do it every month at the very least.

Q. Okay. And we've talked about tracking. That's keeping track of them.

What is trending?

A. Trending is across multiple months, any time period. It can be several months, it can be a year, it can be multiple years, over the lifetime of a product.

So trending is looking at is it increasing, the rate -- monthly rate, is it increasing, is it decreasing, is it changing over time.

Q. Okay. Now, you -- we've talked about internal tracking and trending, and we'll talk about rates in a minute. We've talked about information that you report to the FDA.

The jury's heard this term before, but would you tell them, what is the MAUDE, M-A-U-D-E, database?

A. It's an acronym that describes -- when we submit these MDRs to the FDA, not right away but over a period of time, they put them up on this database. So it's publicly available. You can search it. You can look for those records, and so they're in their own database. So it's nicknamed the MAUDE. It's -- I've forgotten --

Q. Don't worry about it.

A. -- what it stands for now, but...

Q. Does the FDA track adverse events reported to every IVC

manufacturer?
A. Yes. I've seen them on there.
Q. Okay. And so the MAUDE database is not just Bard's reports to the FDA about its IVC filters?
A. No. It's, to my knowledge, all IVC filters and all products.
Q. And it's not -- okay. It's not just IVC filters?
A. No.
Q. So it's a database that if you were going to search it, you would be able to search it by product?
A. You can search by manufacturer, product, any of the key data fields.
Q. Okay. During the time that you were responsible for quality at BPV, did you ever -- were you ever contacted by the FDA and told that Bard's rates were out of line or higher than its competitors' rates?
MR. O'CONNOR: Objection. Calls for hearsay and irrelevant.
THE COURT: Overruled.
THE WITNESS: No. I wasn't contacted by them.
BY MS. HELM:
Q. Now, we've talked about these adverse events, and the jury's heard a lot about Bard's internal documents and internal investigations.
Does Bard share these adverse events, these rates that

you calculate and the information that goes into the rates, do you share that rate number with physicians?
A. No.
Q. Why not?
A. Well, because per FDA, anything like that is considered advertising. And the rates being as low as they are compared with published literature on the same types of failure modes could be construed as advertising. And so it has to be clinically based, for one, in like a clinical study or even a review of other clinical studies to be considered publishable to clinicians.
Q. On occasion, does Bard review the MAUDE database to look at information relating to competitor filters?
A. Yeah. Of course.
Q. Why do that?
A. Well, if we called them up, they're not going to answer how many complaints they have. So the best available information is public available information, so we would go to MAUDE. You search on there to see what failure modes or what events are happening to their devices.
Q. Based on your experience, do you believe that Bard can share its analysis of its rates versus competitors' rates based on the MAUDE database with doctors?
A. No. Because there's a disclaimer against that right on the MAUDE database front page that says comparison of products

using this data is invalid.
Q. Are you familiar with how other IVC manufacturers process their complaint files?
A. No.
Q. Are you familiar with their reporting -- their internal reporting requirements?
A. No.
Q. So do you know if other product manufacturers report every single event the way Bard does?
A. I don't know if they do.
Q. Do you have available to you other competitors' sales records?
A. We do. Again, I know the acronym but not what it stands for. IMS is typically -- I think it's a service that provides estimates of competitors' sales figures.
Q. If you tried to do an analysis of Bard's rates versus competitors' rates, other than being a data point for you, would that tell you anything?
A. It's, I guess, interesting. But those -- I mean, certainly my peers and myself, our management and others know that there's significant limitations to doing that. It's apples and oranges.
Q. Is it scientifically valid?
A. No.
Q. So you look at MAUDE sometimes and you see how your

competitor's doing. Can Bard share information about its competitors' rates with doctors? Can you say, "We calculated this, and look at it"?

A. No. No. You can't share someone else's rates. That would -- we'd be in trouble for that from FDA.

Q. Does Bard include rates relating to adverse events in the warnings or information it provides to doctors?

A. I'm sorry, I didn't hear the first part.

Q. Does Bard include rates in the warnings or labeling that it provides to doctors for its IVC filters?

A. It does based on clinical collected data, clinical trials.

Q. But what about the adverse event rates that you calculate? Are those included in the labeling?

A. They're not.

Q. And this labeling or warning, the jury's again heard this story -- I mean this acronym, another one, IFU. What does IFU stand for?

A. Instructions for use.

Q. And is that the document that goes with the IVC filter to the doctor?

A. It goes with every -- every product that's distributed, correct.

Q. And would it be appropriate for Bard to include rate calculations based on MAUDE, or even its own rate calculations that were not based on a clinical study, in an IFU?

A. No.
Q. Why not?
A. Well, because, one, those IFUs, during our submission process to get the device cleared, go to FDA. They review those. They wouldn't allow that.
Q. In your over 20 years of experience in the medical device industry -- well, let me back up.

In your time working with IVC filters, are you aware of any IVC filter device manufacturer that has included its internal -- let me start all over. I'm sorry. I just got tied on my own tongue.

In your experience in the IVC industry or working for Bard, are you aware of any IVC device manufacturer that has included its internal complication rates in its IFU distributed to physicians?
A. No.
Q. The jury's seen at least one document that had competitors' rates on it and Bard's rates on it. Again, what is your source of competitors' rates?
A. It would be the MAUDE database at best. So given its limitations, we would use those numbers tabulated above what the estimated sales figures might be from another source and try to get some guesstimate rates.
Q. Okay. And what would you use those for?
A. To see if they're reporting the events, honestly. Looking

for if they're reporting the same events.

But beyond that, scientifically, there isn't much value in comparing them. We wouldn't -- as part of our system, it wouldn't be valid to make a determination of a field action based on the comparison of those. Because I don't -- I don't know how they reported them, what the basis for the data was.

Q. Okay. We also saw that Ms. Wong, at least in one instance, compared different Bard filters to one another.

A. Yes.

Q. And do you sometimes do analysis of rates between different IVC filters?

A. Of course.

Q. Okay. And there's been some suggestion in this case that the rates for the Simon Nitinol filter are -- the complication rates are lower than they are for the G2X or the Eclipse filter.

Based on your experience, do you think that's a fair comparison to make?

A. Well, they have different indications, so no. Because they are both filters, but they have different design attributes, they have different performance characteristics, and they have different intended uses.

So that coupled with knowing how the retrievable devices are often identified in retrieval as asymptomatic, as an associated situation, being that Simon Nitinol doesn't get

retrieved, no one's necessarily looking at those or following up with those unless there's a symptom.

So they wouldn't be valid to compare head to head. Again, it's like apples and oranges.

Q. But, again, why do it? We've seen documents where it's done sometimes. If you're comparing apples and oranges, why do the comparison at all?

A. It's still our device. It's still a filter. So it's a data point. I know we've done comparisons of different product lines as well across my time at BPV.

Q. Okay. Let's go back and talk about rates again.

The -- and it's math. And I'm not going to pretend to be good at math, but we're going to talk about fractions just a little bit.

When you're comparing rates, and we saw it with Ms. Wong, the numerator or the top half of the fraction would be the number -- what would that be?

A. The number of reported complaints.

Q. And the bottom half, or the denominator of a fraction, what would that be?

A. The number of units distributed.

Q. And you say distributed. That's the number of -- is that the number of products sold?

A. Yes.

Q. Okay. And why do you use sales for your denominator?

A. Because that's how many we know are the population of devices. That's what we have data -- easy access to that data as well. We have confidence that that is correct.

Q. Do you have a concern that using sales numbers as the denominator, the bottom number, in calculating rates might artificially lower the rates because not all filters sold are actually implanted?

A. True, that being a small percentage. In my years of experience, higher-priced devices don't sit on shelves a lot. They get used or they get returned.

So we take the returns out of those numbers when we calculate them so that we know that we're still accounting for that.

Q. Is it the best information you have available?

A. It is the most reliable, best information we have.

Q. We also have heard and the jury's been told about underreporting of adverse events. Are you familiar with that concern in the industry?

A. Yes.

Q. Okay. Can you account for underreporting?

A. With a certain X factor or a certain percentage, no, because in my experience, again, it varies across product types, product lines. Because, again, they don't -- if they're lifesaving devices, if they're highly critical, could have critical failure modes, they're not going to be, in my, again,

experience, underreported as much as something else that would be less affecting a patient.

Typically, the more severe a potential outcome, the greater likelihood it's going to get reported.

Q. And there's also been some suggestions in this case that there's underreporting to the FDA on the MAUDE database. Are you confident that Bard reports everything it's supposed to report to the FDA?

A. I am.

Q. Okay. Let's talk about rates. We're there. We finally talked about them.

MS. HELM: And, Scott, would you pull up 5874, please.

BY MS. HELM:

Q. Mr. Modra, can you see that?

A. I can.

Q. And what is this?

A. It's the reported number of events and sales of the various types of Bard filters across a certain time period.

MS. HELM: Your Honor, may I take a break? There's an issue with this exhibit that I just need to speak with Scott about.

THE COURT: Yes.

MS. HELM: Thank you.

(Discussion off the record.)

MS. HELM: I apologize, Your Honor. I just --

Scott, would you put it back up for the witness, please.

BY MS. HELM:

Q. Mr. Modra, are you familiar with Exhibit 5874?

A. Yes.

Q. And what is this?

A. It's reported events and sales across the various filter product lines.

Q. And for what period of time?

A. It says through December 2016.

Q. So does this document reflect the total numbers from the beginning of a product's life --

THE COURT: Hold on, Ms. Helm. I think we've got a monitor problem --

MS. HELM: I'm sorry.

THE COURT: -- at plaintiffs' counsel table.

MS. HELM: Your Honor --

THE COURT: If you want to stand up, ladies and gentlemen, feel free.

(Discussion off the record.)

THE COURT: Counsel, are we okay to proceed?

MS. REED ZAIC: This situation is all right.

MR. O'CONNOR: Well, this document's just been changed.

Can we approach?

THE COURT: Yes, you can approach.

And you can stay standing if you want.

(At sidebar on the record.)

MS. HELM: I'll explain --

THE COURT: Hold on just a minute.

MR. O'CONNOR: Here's what they sent me last night; now they just blanked something out on me.

MS. HELM: Your Honor, I did. And the reason why I did was based on your ruling on Mr. Rogers' opening statement about -- he made a -- he had a slide in his opening statement relating to pulmonary embolism with death, and you said he wasn't able to use it. And so based on that --

THE COURT: I said who wasn't able to use it?

MS. HELM: Mr. Rogers wasn't able to use it in his opening.

THE COURT: I'm not remembering that.

What was the issue with you mentioning death?

MR. ROGERS: Let me.

MS. HELM: I'm sorry.

MR. ROGERS: It was a little bit different issue, Your Honor. The slide that we had said 99.99 percent effective, and it's based on this data, that that's the reports of PE deaths that Bard receives.

But your issue was, well, you know, does that mean that you know for sure that --

THE COURT: Right.
MR. ROGERS: -- 99 percent of filters caught a clot.
THE COURT: But what I didn't let you put up was 99.9 --
MR. ROGERS: Correct.
THE COURT: -- percent effective in catching pulmonary emboli; right?
MR. ROGERS: Correct. That is correct.
THE COURT: So what has that got to do with this --
MS. HELM: This is the basis of what his slide was, and so I -- out of caution, I felt like it was not -- we weren't allowed to use it.
THE COURT: Do you object to their using this entire slide?
MR. LOPEZ: No. I want them to use it.
MS. HELM: Okay. Then we'll correct it, Your Honor.
THE COURT: Okay.
MS. HELM: I was just being cautious.
(End of discussion at sidebar.)
THE COURT: Thank you.
BY MS. HELM:
Q. Mr. Modra, would you explain to the jury what this document is, please.
THE COURT: Well, are you going to have him testify about it? It hasn't been moved into evidence yet.

MS. HELM: Your Honor, I think I have to ask the foundation questions to get it in.

THE COURT: Okay. I just didn't know if that was what you were doing or you were actually moving on to the document.

BY MS. HELM:

Q. What is this document?

A. It's a summary of reported events and sales numbers and calculated rates for each of several complications for each of the filter types.

Q. And what time period does this document cover?

A. It says sales through December '16.

Q. Is this a document that is created and maintained in the regular course of business at Bard?

A. It would be.

Q. And was it created and maintained by the quality department you were responsible for in your role as vice president of quality?

A. Yes.

Q. And is it information that is derived from complaint files, medical literature, sales representatives, and the other sources of information that's used to monitor adverse events at Bard?

A. It is.

Q. And is all the data that's collected maintained in a database?

A. It is.
Q. And was the data in the database used to create this chart?
A. Yes.
MS. HELM: Your Honor, at this time I move to admit Exhibit 5874.
MR. O'CONNOR: No objection.
THE COURT: Admitted.
(Exhibit No. 5874 admitted into evidence.)
MS. HELM: May I publish, Your Honor?
THE COURT: You may, but let's talk for just one more minute.
Counsel.
(At sidebar on the record.)
THE COURT: Mr. O'Connor, I think the jury can hear what you're saying. You just said, "I don't think I can see any way to object to this." Nobody was pushing on the mic. I know the jurors with the headphones heard it.
And, in fact, I should have mentioned this morning, I forgot to, I got an email from Trish, our court reporter this morning, saying that she can hear counsel whispering in her headphones at counsel table. And if she can, then jurors with headsets on can, so just be careful about pushing the mute button and whispering. I didn't need to hear it on the mic; I could hear it. Just push it a little bit softer.
MR. O'CONNOR: Oh, okay. I can't hear them whisper,

so they're whispering to me and I can't hear it.

THE COURT: You'll have to solve that problem otherwise.

(End of discussion at sidebar.)

THE COURT: Thank you.

All right. 5874 is admitted.

MS. HELM: May I publish, Your Honor?

THE COURT: Yes.

MS. HELM: Scotty, can you --

BY MS. HELM:

Q. Mr. Modra, as of December of 2016, what was the fracture rate for the G2 Express or G2X filter?

A. It was .21 percent.

Q. And as of December '16 -- of 2016, what was the fracture rate for the Eclipse filter?

A. .17 percent.

Q. And as of December '16, what was the fracture rate, just for comparison, for the Recovery filter?

A. .84 percent.

Q. As of December 2016, what was the migration rate for the G2X filter?

A. .11 percent.

Q. What was the migration rate for the Eclipse filter?

A. .08 percent.

Q. Okay. And it just says migration there.

A. Correct.
Q. And the jury's heard about different types of migration. They've heard about caudal migration and cephalad migration. Does that category include both?
A. It does.
Q. And what was the migration rate for the Recovery filter?
A. .29 percent.
Q. Thank you.
As of December 2016, what was the perforation rate for the G2X filter?
A. .18 percent.
Q. And what was the perforation rate for the Eclipse filter?
A. .15 percent.
Q. And by way of comparison, what was the perforation rate for the Recovery filter?
A. .3 percent.
Q. As of December 2016, what was the tilt -- the rate for tilt for the G2X filter?
A. .23 percent.
Q. And what was the rate of tilt for the Eclipse filter?
A. .19 percent.
Q. And by comparison, what was the rate of tilt for the Recovery filter?
A. .24 percent.
Q. These -- do these rates on here include, for example, a

fracture that also was a migration or a fracture that was also a tilt?

A. They do in that each one is reported in its own category, so fracture, migration, perforation, and tilt.

So if one event includes all four of those things, it's recorded multiple times in each -- so it's recorded in each one of those categories.

Q. So if there was an adverse event in which someone complained of a fracture, a tilt, and a perforation, would it appear in all three of those categories?

A. It would. It would be triple counted.

Q. And, again, when we talked about Ms. Wong's report, Bard -- has Bard analyzed the instances -- at times analyzed the instances of multiple adverse events; for example, fracture and tilt?

A. We have.

Q. And in your experience, are the multiple adverse events, for example, a filter that suffers perforation, tilt, and fracture, are those rates higher or lower than those reflected on the exhibit?

A. They would have to be quite a bit lower than these because they're fractions of the fractions.

Q. Okay. In your experience with Bard, do you believe that these rates, as reflected on this exhibit, include all the adverse events that Bard heard about?

A. Yes.
Q. They include information from all the sources we discussed?
A. They do.
Q. Okay. Does -- are you familiar with the Society of Interventional Radiologists?
A. I am.
Q. And how have you become familiar with that group?
A. I'm most familiar with some of the publications that they've had related to IVC filters.
Q. And do you have -- do employees at Bard attend the Society of Interventional Radiologists conventions or seminars?
A. Quite a few.
Q. And why do they do that?
A. To learn the latest trends and techniques, latest concerns, new product ideas, talk to physicians, learn what SIR is focused on as a group of clinicians.
Q. And I got a little sidetracked there, but let's go back to this.

Are these rates perfect?

A. No.
Q. Is there any way for Bard to calculate perfect rates?
A. No.
Q. Okay. Based on all that we've discussed and the information that's available with Bard, are you confident in the validity of Bard's rates analysis based on the best

information available to it for its IVC filters?
A. I am.
Q. On Tuesday, Mr. O'Connor asked you about a letter that you received or that Bard received from the FDA.
Do you recall that conversation?
A. I do.
Q. And it was -- it was a warning letter. Do you recall that?
A. Yes, I do.
Q. Okay. I want to talk to you about that warning letter. Before we do, let's talk about some more Bard procedures.
Periodically, does Bard do internal audits of your complaint handling system?
A. Yes.
Q. Okay. Do you audit yourself internally, like we're checking on ourselves, or are there other ways that you audit your system?
A. We have an independent auditor internally but that reports directly to the vice president of quality, that doesn't work in any one of the other departments, that conducts the internal audits across all the functions.
We also have a corporate level function, auditing function that visits us at least once a year to review the entire quality system, including the complaint handling, that does audits as well.
Q. Earlier this morning and yesterday, the jury heard some

testimony about the involvement in the FDA after a product is cleared.

After a product -- after an IVC filter, for example, is cleared and on the market, does the FDA do any audits of Bard relating to that filter?

A. Yes. And all products.

Q. And what sorts of audits does the FDA do?

A. Typically, they'll call it a routine inspection, but it's unannounced. So you have to be ready at any time, and FDA will show up at your doorstep. They will show their credentials, and you escort them wherever they want to go.

Q. Do they review complaint files?

A. Extensively.

Q. Do they review your policies and procedures?

A. Yes, they do.

Q. Do they review design methods?

A. They do.

Q. Do they review any root cause analysis done by the company on adverse events?

A. They do.

Q. Does the FDA, in your experience, do they conduct audits of all device manufacturers?

A. To my knowledge, they do.

Q. Okay. And does the audit or the inspection that FDA does sometimes result in a finding by the FDA of deficiencies in

your quality systems?
A. They do.
Q. During your time at BPV, was the company subject to some of these FDA periodic audits?
A. They were. Twice prior to -- yes.
Q. And as a result of an audit, did the FDA issue a warning letter to Bard in July of 2015?
A. They did.
Q. Had that ever happened to you in your function as head of quality before at BPV?
A. No.
Q. How did you react to that warning letter?
A. I spent night and day working to respond appropriately. They have expectations for not just correcting the noted deficiencies but taking a look across your systems, and I take that very seriously. So I spent many hours responding to it and addressing it.
Q. What was it in the warning letter -- what was -- as it related to reporting of rates or reporting of complications to the FDA, what was FDA's concerns? What did they express in the warning letter?
A. Well, they have a regulation that we spoke about, the MDR reportability. And it includes language that describes how to report these events, under which circumstances. But it's written across all medical devices. It's not just IVC filters

only or some other products.

So we have to do some interpretation of what we think they're telling us. They put out a number of guidances to help companies do that, but we had interpreted it one way and they cited us saying no, we expect you to report these kinds of events as well.

So through the warning letter, they cited us for that.

Q. And was the issue the difference between reporting an incident as a serious injury versus a malfunction?

A. It was -- yes. It was reporting it -- not whether or not we had reported those, because we were already reporting fracture, migration, tilt, perforation already. It was we were classifying them as malfunctions when there were certain circumstances where they expected them to be reported as serious injuries.

Q. Was there also an issue in the reporting letter that certain information had not been reported to Bard -- to the FDA?

A. Yeah. They noted that even though we had a procedure that said do at least a minimum of three attempts to get more information, what we weren't doing was writing down that we had attempted, number one, an attempt on Tuesday; number two, attempt on Wednesday; three attempt on the follow-up.

We weren't properly documenting that we were doing those three attempts. So they couldn't, in an independent

examination, determine if we had done the three. So we changed our practices to have very definitive documentation of those multiple attempts of getting that information.

The second part was, even though we were asking for it, we weren't documenting a patient's age at the time of implant, weight, and some other patient attributes.

Q. Did the criticisms that the FDA -- the warning -- that came in the warning letter have to do at all with the failure on Bard's part to report an event that involved a patient injury?

A. No.

Q. Did the concerns expressed in the warning letter in any way relate to Bard's failure to report instances of migration to the FDA?

A. No.

Q. Did it relate in any way with Bard's failure to report fracture to the FDA?

A. No.

Q. Did it report in any way about Bard's alleged failure to report tilt to the FDA?

A. No.

Q. And the same thing: Did it relate in any way for Bard's alleged failure to report perforation to the FDA?

A. No.

Q. Okay. As part of the FDA inspections and the warning letter, did the FDA review any of Bard's files?

A. Yes. They reviewed quite a bit of our files.
Q. And did you have to copy and box up paper files and send them to the FDA?
A. They carted out over 20 bankers boxes worth of design, manufacturing, complaint files.
Q. And Bard fully cooperated -- did Bard fully cooperate with the FDA?
A. Absolutely.
Q. And you produced your design files?
A. Every -- every last one of them.
Q. And you produced your complaint files?
A. Yes.
Q. And those related to the G2 filter?
A. Yes.
Q. Did those relate to the G2X filter?
A. Yes.
Q. And did those relate to the Eclipse filter?
A. Yes.
Q. And the FDA took whatever they wanted, complaint files, design files, whatever they wanted relating to those three filters?
A. Absolutely. Whatever they ask for, they get.
Q. After the FDA had the opportunity to review all of those files and Bard's data, did the FDA come back and say that there was anything wrong with the design of those filters?

A. No.
Q. Did the FDA come back and say there was anything wrong with Bard's IFU or the warnings that accompanied those filters?
A. No.
Q. Did Bard ultimately satisfactorily respond to the FDA's concerns from the warning letter?
A. We did.
Q. And was there a closeout letter where the FDA said you've -- our investigation is complete, and you can go on back to your regular course of business?
A. Yes.
MS. HELM: Okay. Scott, would you pull up 5872, please.
BY MS. HELM:
Q. Mr. Modra, do you recognize this document?
A. I do.
Q. And what is this?
A. This is the typical closeout letter that was sent to our CEO.
Q. And is this document now maintained in the correspondence it receives -- that Bard receives from the FDA?
A. It is.
Q. And is it maintained in the course of business at Bard?
A. It is.
MS. HELM: Your Honor, at this time I move to admit

5872.

MR. O'CONNOR: No objection.

THE COURT: Admitted.

(Exhibit No. 5872 admitted into evidence.)

BY MS. HELM:

Q. Mr. Modra, in your 24 years in the medical device industry, much of it in product quality, if you ever felt that a product's risks outweighed the benefits, what would you do?

A. I would take action on it.

Q. And in your time at Bard, when you were responsible for the quality of Bard's retrievable IVC filters, did you ever reach that conclusion?

A. No.

Q. I want to go back and ask you one more question. I'm almost finished.

MS. HELM: Scott, would you pull up 43 -- Exhibit 43, please. I'm sorry.

Your Honor, shame on me. Before I take it down, may I publish 5872?

THE COURT: You may.

MS. HELM: Thank you.

Now may I take it down?

THE COURT: Yes.

MS. HELM: And, Scott, would you please pull up Exhibit 443 and specifically page 18.

BY MS. HELM:
Q. Mr. Modra, remember this document?
A. I do.
Q. If it's been represented that this document reflects that 36 percent of Bard's G2 filters perforate, is that an accurate representation of the document?
A. No.
Q. And, again, what does that 36 percent relate to?
A. Because this is the fracture analysis, it's 36 percent of the reported fracture events also had reported perforation.
Q. And, again, that was .06 percent?
A. The fracture rate was .06 percent.
Q. Okay. So I'm not going to ask you to do the math, but if you wanted to calculate the number of G2 filters in this analysis that had both fracture and perforation, you would take .06 and basically divide it by three? 36 percent?
A. Yes.
Q. And so that would be a number that has .00 before you get to a --
A. It would be .02-ish.
Q. .02, okay.

And the same thing with tilt and the same thing with caudal migration; those are percentages of that .06 fracture rate that had that additional complication. Is that right?
A. That's correct.

Q. Okay. And, again, all of those numbers would be much smaller?
A. Yes.
Q. And is that consistent with what you've seen in your years at Bard as far as filters suffering or resulting in more than one complication rate?
A. Yes.
Q. Are those numbers higher or lower than the numbers for each complication rate?
A. They would all be lower.

MS. HELM: Thank you. No further questions.

THE COURT: Cross-examination?

MR. O'CONNOR: Yes, Your Honor. Thank you.

CROSS-EXAMINATION

BY MR. O'CONNOR:
Q. Welcome back, Mr. Modra.
A. Thank you.
Q. Good to see you again. Again, I'm Mark O'Connor.

Let me start out just going back to something you started way back in the beginning of your testimony with Ms. Helm, and if we could talk about this Surgeon General report.

MR. O'CONNOR: Felice, if you could put up 7411.

BY MR. O'CONNOR:
Q. Now, Mr. Modra, I think you said that you have -- you keep

yourself apprised of the current state of the literature out there as well; correct?
A. Uh-huh. That's correct.
Q. Now, this was in 2008, this report from the Surgeon General.
MR. O'CONNOR: May I publish this, Your Honor?
THE COURT: You may.
BY MR. O'CONNOR:
Q. Correct?
A. Correct.
Q. And you know that since 2008, there have been a number of articles written about filters and including Bard filters; correct?
A. Correct.
Q. I mean, since 2008, Nicholson wrote an article about the prevalence of G2 failures. You've seen that; true?
A. I'm aware of that.
Q. And you're also aware of the PREPIC study that has come out since 2008 that questioned whether filters were even effective in what they were intended to do. You've seen that article; correct?
A. I believe I've seen that yes.
Q. And also, you are aware of an Angel article that talks about where Bard is in relation to other filters in terms of failures like fracture; correct?

A. I don't recall what year or when that was.
Q. Angel, you've heard of the article?
A. I don't know if I have.
Q. Well, the point is, there have been numbers of articles since this 2008 Surgeon General report; correct?
A. Correct.
Q. And you're aware of a number of those articles that address Bard filters specifically; true?
A. Yes.
Q. Thank you.
MR. O'CONNOR: Felice, let's go to Exhibit 2248. Thank you.
May I publish, Your Honor?
THE COURT: You may.
BY MR. O'CONNOR:
Q. And, Mr. Modra, you were questioned quite a bit about this and other documents.
MR. O'CONNOR: Go to page 2, Felice.
BY MR. O'CONNOR:
Q. And this is a report by Natalie Wong; is that correct?
A. That's correct.
Q. Natalie Wong still works for Bard, doesn't she?
A. She does.
Q. And certainly Natalie Wong is capable of talking about what she did and why she did things; true?

A. Yes.
Q. And she was head of the caudal -- she led the caudal migration team back in this period of time for the G2?
A. I don't know if that was what she was leading. I know that she had put this report together.
Q. Well, let's go to page 20.
Are you aware that Natalie Wong testified that the unacceptable risks that she showed here, she characterized those as alarming if they're in a Quad 3 or 4?
A. Yeah. By definition, if they're in a Quad 3 or 4 --
Q. It's alarming?
A. I don't know where "alarming" came from, but --
Q. My question is, are you aware that's what she's testified?
A. No.
Q. Now, let's go to page 5 of this document, which is back in the time period of March 2, 2006.
Now, I think you told us that you took the number of complaints and you used that and divided it with the number of units distributed. Did I understand that correctly?
A. That's correct.
Q. Units distributed, though, is not the units that are actually implanted in humans; correct?
A. No.
Q. As a matter of fact, you at Bard don't know how many G2s over the years have actually been implanted compared to sales;

true?
A. We don't know for sure, no.
Q. And you know that there may be some that expired and were never used; right?
A. True.
Q. There may have been G2 filters left on shelves that were never implanted in patients; correct?
A. True.
Q. And you also know that there are patients out there that may have a G2 or G2X filter that has failed and simply aren't aware of it; correct?
A. Asymptomatic, correct.
Q. So in other words, a patient could have a fractured G2, G2X, or even an Eclipse where an arm fractured and embolized to his or her heart and that patient or person not be aware of that; right?
A. That is possible.
Q. And you at Bard have not looked into that issue, have you?
A. I'm not sure what you mean by not have looked into that issue.
Q. Well, you only know about the failures that are reported to you and to MAUDE; true?
A. And to those published in literature with clinical studies.
Q. But unless they're published or unless they're reported, you have no idea how many people are out there with failed

filters, failed Bard filters; is that fair?
A. Correct.
Q. And certainly if you knew the number of filters that were actually implanted, that would change the way you calculate rates; true?
A. If we were accurately able to do that, correct. But --
Q. But Bard has never set forth a program, have they, to where they have notified doctors and said that "We'll pay to get every patient that has ever received a G2 back, and we want you to do imaging and monitoring them to see if they have a failed filter"?
That has never happened, has it?
A. No.
Q. But certainly if Bard wanted to know how many filters had actually failed, there are things Bard could do, aren't there?
A. There are. But that's assuming that the failures are --
Q. Well, if Bard wanted --
A. -- injurious.
Q. -- to know if filters were breaking and going in people's lungs and hearts, they could certainly get the cooperation of the medical community and pay for a study to monitor patients that had received the G2s, the G2X, and the Eclipse since day one; right?
A. All of that is possible.
Q. But it hasn't been done, has it?

A. No.
Q. And so there are patients out there who may be going in and be totally unaware of a fracture to the heart, but because of an incidental CT scan, learn that a strut was in their heart and were able to get the help they needed just because of some coincidence.
You're aware of that happening; right?
A. I've heard of that occurring.
Q. Let's go to Exhibit 443.
Now, this is another document that you and Ms. Helm were talking about. Do you recall that?
A. I do.
MR. O'CONNOR: May I publish, Your Honor?
THE COURT: You may.
BY MR. O'CONNOR:
Q. And, again, this is a document that was prepared by Natalie Wong back in 2008; right?
A. Yes.
Q. And Ms. Wong still works for Bard; right?
A. She does.
Q. Okay. But the difference between Ms. Wong and you is you were not there in 2006 or 2008; true?
A. I was not there at the time, no.
Q. You weren't there in the time that the people at Bard were dealing with complaints and increasing complaints of G2 and G2X

failures; right?
A. I wasn't there at that time.
Q. And certainly you don't know why Natalie Wong did these studies, do you? Or who ordered her to do them?
A. I don't know that, but I know that I've talked to Ms. Schulz, who was her supervisor at the time --
Q. Okay. But what you --
A. -- around the circumstances.
Q. What you do know about rates and these things that you have done on rates yourself is what you've told us. Bard does not share those with the medical community; right?
A. Correct.
MR. O'CONNOR: Felice, let's go to page 2.
BY MR. O'CONNOR:
Q. Now, by this time, a different -- one difference from the previous study we just saw that was in 2006 is that this document deals with G2 and G2X filters; correct?
A. Correct.
Q. And when we look at total units distributed, again, those are sales of the combined sales of G2 and G2X; right?
A. Yes.
Q. And nobody separated these, did they? They didn't -- this report doesn't show a difference or separate the G2 from the G2X?
A. No.

Q. It's lumped together?

And here, there's a total of 56 commercial complaints. Do you see that? You talked about that earlier.

A. I see that, yes.

Q. And then if we go to page 18, Ms. Wong went ahead at someone's direction and compared the G2 trend and how it was related to the RNF trend of failures.

Do you see that?

A. I do.

Q. And you're not here to criticize Ms. Wong's work, are you?

A. No.

Q. You understand that Ms. Wong was doing her job and trying to be accurate when she was doing it; right?

A. I'm sure she was.

Q. But something --

MR. O'CONNOR: If we go back to page 2, Felice.

BY MR. O'CONNOR:

Q. Something that is noteworthy at this point for our next question is that the total numbers of units distributed was 100,826. And that was back in 2008; right?

A. Correct.

MR. O'CONNOR: Felice, let's put up Exhibit 1940.

I think this is in evidence. May I publish this to the jury, Your Honor?

THE COURT: Yes.

BY MR. O'CONNOR:

Q. Now, Mr. Modra, are you familiar with this document?

A. I am.

Q. And this is, if we look down in the left-hand corner of Exhibit 1940, this is Bard data from Trackwise, not MAUDE, through July 2010.

Do you see that?

A. I do.

Q. And as we look at this, we can look at Bard filters and we can look at the total number of sales; right?

A. I see that column.

MR. O'CONNOR: Let's go to that column, Felice, for G2 and G2X.

BY MR. O'CONNOR:

Q. So by 2010, sales for G2X and G2 had increased; correct?

A. Yes.

Q. And if you combine those sales, you come up with about 162,000. Does that make sense?

A. Yeah, it does.

Q. And, again, that's just sales. No way to know how many of those filters have been actually implanted in patients; right?

A. No.

Although to my previous statement --

Q. Pardon me?

A. I said although to my previous statement, with a

higher-priced device, they don't typically sit around.
Q. Well, but you just don't know. And you can't come and tell this jury how many G2 and G2Xs were implanted; correct?
A. I can't.
Q. And you can't tell this jury how many filters were taken back? We know that filters like the market -- went on the market like the Meridian; right?
A. I don't know that number committed to memory, no.
Q. And you don't know how many hospitals out there reported to people at Bard they actually had G2 and G2X sitting on their shelves that were expired, do you?
A. I don't.
Q. You knew that these filters had expiration dates; correct?
A. I'm familiar with that, yes.
Q. And you do know there were times where Bard instructed the sales staff to tell healthcare providers in hospitals to stop using certain filters and switch over to a new brand. You're aware of that, aren't you?
A. Yeah. And I'm aware that some of their responses were that they wanted to continue using the G2.
Q. I move to strike because I just asked you a yes or no. I think you answered it.
THE COURT: Overruled. If you want him to answer yes or no, tell him.
MR. O'CONNOR: Okay. Thank you, Your Honor.

In any event, let me -- if we go to the number of fractures for G2 and G2X. Do we find those?

MR. LOPEZ: She highlighted them.

MR. O'CONNOR: Oh, they're down there, okay.

There's 195 -- oh, I'm just looking at for G2 and G2X.

Oh, I see, okay. Thanks. I was looking over here. Thank you.

BY MR. O'CONNOR:

Q. Anyway, so now if we look at the column Total Fractures -- I was looking at the wrong place -- we see for the G2 there's 143. Do you see that?

A. I do.

Q. And for the G2X, there's 32. Do you see that?

A. I do.

Q. And now there's 175 fractures based upon 162,000 sales. Is that right?

A. Yes.

Q. And that means that the rate has increased since 2008; right?

A. Correct.

Q. As a matter of fact, you could calculate that out and figure out how much it increased by, couldn't you?

A. Yes. Comparing the two.

Q. And you're also aware that there are still patients with G2s and G2Xs in them; correct?

A. Correct.
Q. And one thing you can't tell us on any of these studies is when these patients who had experienced these fractures received their G2 or G2X; correct?
A. We could by looking at the complaint files.
Q. Okay. But you didn't do that to come here and talk to the jury today, did you?
A. Um --
Q. You didn't look at the complaint files for each of these 175 fractures, did you?
A. No, I didn't.
Q. Okay. Because it could mean a number of different things. It could mean, for example, that the G2 and G2X, the risk of fracture increases the longer the filter remains in the patient. That's something that you could find out in a trending report, couldn't you?
A. We could. I also know there's published studies that say most of those occur within the first 60 or 90 days. Most adverse events.
Q. Well, sir, here we see an increase from 2008 in both sales but a greater increase in the number of fractures. True?
A. True.
Q. And, again, simply don't know, of the total number of sales, how many of those were actually implanted. Fair?
A. Fair.

Q. But what you can tell the jury is that if you go by 2008 and now you look at a Bard document in 2010, you can tell that jury that the rate of fracture in G2 and G2X had increased in that period of time through 2010; true?
A. Correct.
Q. And you look at trends to understand the future as well; correct?
A. True.
Q. So one thing that you can learn from this is that if there's patients out there today with G2, G2X, or Eclipse, that they are at a high risk of having their filter fracture. Correct?
A. No.
Q. An increased risk?
A. No. That's extrapolating outside of the data field. That would be improper analysis.
Q. So you haven't trended that. True?
A. Because it wouldn't be --
Q. Have you trended that, yes or no?
A. It wouldn't be a valid --
Q. Have you --
A. No, I haven't.
Q. Thank you.
MR. O'CONNOR: Let's go to the FDA warning letter.
May I publish 1680, Your Honor?

THE COURT: You may.

MR. O'CONNOR: Can we go to page 4, Felice?

BY MR. O'CONNOR:

Q. And, Mr. Modra, just so we can leave this issue today, the FDA warned Bard about not having adequate procedures to evaluate root cause analysis. That was one of the topics in the warning letter; correct?

Looking at paragraph -- subparagraph a. We talked about this a couple days ago.

A. Yes, in that they included the statement of a device component provided by a supplier.

Q. Part of the warning letter dealt with procedures that Bard did or did not have regarding root cause analysis; correct?

A. That's correct.

Q. And another part of the warning letter was how Bard was filing complaints, calling complaints that should have been serious injury as malfunctions; true?

A. True.

MR. O'CONNOR: That reminds me, can I have the Ciavarella --

BY MR. O'CONNOR:

Q. And, Mr. Modra, you weren't there in 2005, 2006, or 2008 when Natalie Wong was doing the analysis. I'm going to show you an email from then-medical director David Ciavarella.

When you came to Bard and you were doing your

background and you were looking back at the history, did you look to see who the medical directors were?

A. Yes.

MR. O'CONNOR: Okay. May I publish Exhibit 991?

THE COURT: Yes.

BY MR. O'CONNOR:

Q. This is an email from Dr. Ciavarella. Have you seen this before?

A. I'm not sure if I've seen it in its entirety.

Q. All right. Well, let's just look at how Dr. Ciavarella felt about G2s.

MR. O'CONNOR: Felice, can you highlight "I would like to look"?

BY MR. O'CONNOR:

Q. And here is Dr. Ciavarella saying: The G2 is a permanent filter. We also have one, the SNF, that has virtually no complaints associated with it. Why shouldn't doctors be using that one rather than the G2?

Do you see where I read; and did I read that correctly, sir?

A. Yes.

Q. And were you aware before today that the medical director of Bard questioned why doctors were not using the Simon Nitinol filter because of his awareness of the G2 complaints? Were you aware of that, yes or no?

A. Yes.
Q. Thank you.
And are you aware that Dr. Ciavarella has said that MAUDE data is underreported?
A. Yes, I'm familiar with that.
Q. And are you aware that Dr. Ciavarella has testified that only 1 to 5 percent of actual failures are actually reported? Are you aware of that?
A. I'm aware of that.
Q. And in terms of tracking and trending and the report you showed and talked to about with Ms. Helm --
MR. O'CONNOR: Can we go to Exhibit 5874.
BY MR. O'CONNOR:
Q. First of all, Mr. Modra, the G2, the G2X, and the Eclipse were all launched, promoted, and marketed as permanent filters. Correct?
A. I can't remember if they were originally, but I believe so because they had the indication for retrievability later.
Q. Okay. Let me ask you to assume that each one of those filters were represented as Bard as being permanent filters that should be able to last the duration of a patient's life. You have no reason to disagree with that; fair?
A. That's correct.
Q. And today, in Exhibit 5874, you told Ms. Helm this is something that you prepare in the regular course of your

business and your position.

Did I understand that correctly?

A. In my position as the VP of quality at the time, yes.

MR. O'CONNOR: May we display it to the jury, Your Honor?

THE COURT: Yes.

BY MR. O'CONNOR:

Q. And you looked at the Recovery filter, you looked at the G2 filter, you looked at the G2 and the G2X, the Eclipse, the Meridian, and the Denali. And you were -- you didn't look at the Denali?

A. I was asked questions about the G2 Express, the G2, and the Recovery.

Q. I apologize.

Your report deals with all of those filters; correct?

A. Correct.

Q. But what's missing from this report is the Simon Nitinol filter. There's nothing about the Simon Nitinol filter; true?

A. Correct.

Q. Thank you.

And by the way, Mr. Modra, during the time you were tracking and trending, Bard never did a long-term clinical trial for the G2X. True?

A. Correct.

Q. And also, while you were doing your tracking and trending

during that time, Bard never did a long-term clinical trial for the Eclipse filter; correct?

A. I can't remember. No, I don't think so.

MR. O'CONNOR: Thank you.

I think that's all I have.

THE COURT: Redirect?

MS. HELM: No questions, Your Honor.

THE COURT: All right, thanks.

Mr. Modra, you can step down.

(Witness excused.)

THE COURT: If you want to stand up while we're waiting for the next witness, feel free.

MR. CONDO: Your Honor, we will call Dr. Clement Grassi.

THE COURTROOM DEPUTY: Sir, if you'll please come forward and raise your right hand.

(The witness was sworn.)

THE COURTROOM DEPUTY: Could you please state your name and spell it for the record, sir.

THE WITNESS: Yes. Clement Grassi. C-L-E-M-E-N-T, G-R-A-S-S-I.

THE COURTROOM DEPUTY: Thank you, sir. Please come have a seat.

CLEMENT GRASSI, M.D.,

called as a witness herein by the defendants, having been first duly sworn or affirmed, was examined and testified as follows:

DIRECT EXAMINATION

BY MR. CONDO:

Q. Good afternoon, Doctor. Would you please tell the ladies and gentlemen of the jury who you are and what subjects you are here to talk about today, please.

A. Yes. My name is Clement Grassi. I am a practicing physician, interventional radiologist, and I am here to comment on and discuss the guidelines for percutaneous inferior vena cava filter placement which have been published by the Society of Interventional Radiology, known as the SIR.

Q. And the opinions that you intend to share with the jury today, have you formed them to a reasonable degree of medical certainty?

A. Yes.

Q. Let's talk a little bit about your background and experience that allows you to comment on the SIR -- SIR guidelines.

You've told us that you're an interventional radiologist, but let's go back. Where did you go to college, sir?

A. I went to Harvard College.

Q. And where did you attend medical school?

A. At Tufts University School of Medicine.
Q. And after medical school, did you complete an internship for additional training?
A. Yes, I did. I stayed in the local area and completed my first postgraduate year one at Massachusetts General Hospital, also in Boston.
Q. And is Mass General one of the hospitals affiliated with Harvard University?
A. Yes. It is one of the major teaching hospitals for Harvard University, Harvard School of Medicine.
Q. And are there other major teaching universities associated with Harvard University?
A. Yes, there are other hospitals affiliated with it.
Q. Is Brigham and Women's one of those hospitals, sir?
A. It is.
Q. We'll talk about that in a second.
After you completed your first year of your internship, what was -- did you -- did you complete a residency?
A. Yes. I continued after my first postgraduate year one to continue as a resident in radiology. And that was at the Beth Israel Deaconess Hospital in Boston.
Q. And when did you complete your residency in radiology, sir?
A. In radiology, I graduated in 1985.
Q. And is Beth Israel Deaconess Hospital also affiliated with

Harvard University?
A. Yes, it is. It is also one of their major teaching hospitals.
Q. And then did you complete fellowship training after you completed your residency?
A. I did. I applied to and was accepted for fellowship in interventional and cardiovascular radiology at the Brigham and Women's Hospital, and I was there for a two-year fellowship.
Q. And when did you complete that fellowship, sir?
A. And that was in -- it continued between 1985 and 1987, completed in 1987.
Q. And after completing your fellowship training, did you hold any academic appointments?
A. I did. I was invited to stay on in a job position as a staff radiologist at the Brigham and Women's Hospital. And that is, as we've said, a teaching affiliate of Harvard Medical School, so that I had an academic appointment as an instructor in radiology and in years subsequent to that as an assistant professor of radiology.
Q. And what period -- over what period of time did you hold those academic appointments, sir?
A. That was between 1987 and up to 2001.
Q. And where do you currently work?
A. I am currently with Partners Healthcare, and I also work with Hallmark Health.

Q. And you are, in fact, licensed to practice medicine?
A. I am. I'm a licensed physician in the state of Massachusetts.
Q. And are you board certified in any medical specialty?
A. Yes. I'm board certified in radiology. And as well, I have what is termed a certificate of added qualifications in interventional radiology, which requires additional testing, also granted by the American Board of Radiology in the U.S.
Q. Let's start first with board certification. What does it mean to be board certified, sir?
A. Well, to be board certified, as in radiology, means to have completed training in a residency program over several years, having passed a number of tests during residency, and then having sat for both written and oral examinations in the specialty.
Q. And what was required to receive the additional certificate beyond your board certification that you were awarded by the American Board of Radiology?
A. When the CAQ or the additional certificate was instituted, a number of requirements were attached to that; that is, having completed an approved or certified fellowship, having experience and training in the field, and again, having sat for and successfully completed a written examination.
Q. How long have you been practicing medicine?
A. Approximately 38 years.

Q. And how long have you been board certified?
A. I've been board certified -- you can subtract the -- let's see, the training number of years, so I've been board certified since 1987.
Q. And have you held any directorship positions in vascular or interventional radiology at any hospitals?
A. Yes. I was the director of vascular radiology at the Boston VA Medical System in Boston for a period of years. And subsequent to that, between 2009 and 2011, I took a job promotion position and was the director of vascular and interventional radiology at the UMass Memorial Medical Center in Worcester, Mass.
Q. And have you served as an educational coordinator for the curriculum of students matriculating at Harvard Medical School?
A. I have. During the time that I had the academic appointment, as we've discussed, in Harvard Medical School, I was the director -- coordinator, I should say -- coordinator for students, residents, and fellows in the training program.
Q. Students, residents, and fellows in cardiovascular and interventional radiology?
A. That's correct. I interacted with them.
Q. And did the curriculum at Harvard include the subjects that you're going to be discussing with the jury, including the SIR guidelines?
A. Yes.

Q. Now, are you being compensated for your time appearing here today?
A. Yes.
Q. And what compensation are you asking for on an hourly basis, sir?
A. On an hourly basis, I'm being compensated $350 an hour.
Q. And does that include travel time to and from Phoenix to testify?
A. It would. Testimony and related work.
Q. Now, is consulting and testifying in litigation matters like this one your principal source of your professional income?
A. No, it isn't.
Q. What is your primary source of your professional income?
A. My primary source of my income is the practice of interventional radiology, which I work at. And --
Q. And how frequently do you consult in litigation matters like this?
A. Infrequently.
Q. And why do you consult, on those infrequent occasions that you do, in matters like this that are headed towards litigation or in litigation?
A. Well, I feel that it is important to weigh in on subjects which are in the field of interventional radiology, which is my specialty. And I feel that it's very important for patients to

have the benefit of the types of image-guided procedures that doctors like myself provide.

Q. And as part of your interventional radiologist practice, do you implant and retrieve inferior vena cava filters?

A. Yes, I do.

Q. What was your earliest experience with an inferior vena cava filter?

A. Well, my interest actually dates back to medical school. I was interested in vena cava filters and became engaged in a clinical project and assisted one of the doctors at Massachusetts General Hospital then in researching a particular clinical project. So my interest actually dates back many years.

Q. And have you published articles on the subject of inferior vena cava filters?

A. I have. I have several peer-reviewed publications and at least 12 articles on the subject of vena cava filters themselves.

Q. Have you served as an investigator for clinical trials?

A. Yes. For example, when I worked at Brigham and Women's Hospital, I was the principal investigator for the clinical trial portion conducted at that hospital, which was for the Simon Nitinol filter.

Q. And does your experience, your long experience with vena cava filters, include all of the devices that have been cleared

by the FDA for use in the United States?
A. Yes. My experience extends to those filters that are accepted for use in the U.S.
Q. And in your patients in whom you plant and retrieve filters, do you believe the filter provides a benefit as a mechanical protection against pulmonary embolisms?
A. I do.
Q. Are you a member of the Society of Interventional Radiologists?
A. Yes, I'm a member.
Q. How long have you been a member of the Society of Interventional Radiologists?
A. I've been a member for now over 25 years.
Q. And if I refer to it as the SIR, you and I can agree that it stands for Society of Interventional Radiologists?
A. Yes.
Q. All right. Thank you.
Now, is there something called a senior fellow within the ranks of the SIR?
A. There is.
Q. And are you a senior fellow?
A. Yes.
Q. And what is the criteria for becoming a senior fellow within the SIR?
A. A senior fellow is an honorary position, and the criteria

are established by the SIR. It includes training in the field, exceptional work in the field, having published articles such as peer review articles, and other demonstrations of additional work or experience in the field.

Q. And have you served on any committees within the SIR?

A. Yes. I've been happy to say that I've been interested and have served and had the honor of serving on several committees, which have included the technology assessment committee of the SIR and the standards of practice committee at the SIR.

Q. And have you held any chair positions on either of those two committees?

A. Yes. I've been pleased to say that I was asked to chair each of those committees in the customary rotation of three years as the chairperson for each.

Q. And what is the focus of the standard and practice committee of the SIR?

A. The standards of practice committee is dedicated to providing guidelines, education, and information on a variety of topics that interact and are part of what we do; that is, imaging-guided interventions for patients.

Q. And is it the focus of the standard of practices committee to inform and educate other members of the Society of Interventional Radiologists?

A. Yes, it is.

Q. Has the SIR standards of practice committee developed

guidelines for interventional radiologists?
A. Yes.
Q. And specifically, have those guidelines been developed for clinicians who place and retrieve IVC filters?
A. Yes.
Q. And were you involved in that project?
A. Yes, I was.
Q. Can you tell us when that project started, please?
A. Yes. That project started in terms of its inception very late in the 1990s and approximately 2000.

The feeling was that there were literally hundreds of publications which were available, but there was no one document that the SIR could identify that summarized or helped practitioners and those who use vena cava filters by way of reviewing and summarizing the world literature.
Q. And why was it felt that reviewing and summarizing the literature on IVC filters would be beneficial to those involved with the placement and retrieval of IVC filters?
A. Well, the SIR felt, I believe correctly, that practitioners really needed guidance, education, and commentary so that they could better treat their patients and be aware of the current issues and how to improve their practice.
Q. And what was the purpose for the development of the IVC filter guidelines?
A. The purpose was really to educate, inform, and summarize

anyone working with IVC filters as to the status of clinical indications, effectiveness, complications, and a variety of information that doctors could use in their individual practices in order to improve.

Q. Were the guidelines written, then, for quality improvement programs within individual clinicians' practices?

A. Yes.

Q. And how were the guidelines -- or how are the guidelines intended or supposed to be used in the medical community?

A. The guidelines are intended to help physicians with quality assurance, so that if he or she were to read that there may be a certain percentage or parameter that really wasn't exactly what they observed in their practice, it would and should trigger a quality assurance review. That is, the particular doctor would look to see whether their practice really was the same as what was recommended by the SIR guidelines.

Q. And when were the guidelines first published, sir?

A. In 2001.

Q. And before then, were there any practice guidelines for interventional radiologists about IVC filters?

A. To the best of my knowledge, no.

THE COURT: All right. We're going to break at this point, Mr. Condo.

MR. CONDO: Thank you, Your Honor.

THE COURT: Ladies and gentlemen, we'll look forward

to seeing you tomorrow morning at 9:00 o'clock, and we'll excuse the jury.

(Jury not present.)

THE COURT: You can step down, Doctor.

Please be seated.

Counsel, is there a time allocation for Kuo, which I think was the only deposition played today?

MS. HELM: 22 minutes for the plaintiff and 8 minutes for the defendant.

THE COURT: And that was the only depo today; right?

MS. HELM: Yes, Your Honor.

THE COURT: Okay. Give me just a minute.

All right, counsel. As of the end of today, plaintiffs have used 27 hours and 49 minutes; defendants have used 12 hours and 28 minutes.

I have a hearing now, so we'll deal with the Rule 50 motion tomorrow morning.

MS. HELM: Thank you, Your Honor.

THE COURT: Anything else we need to address before we break?

MR. LOPEZ: Nothing from us, Your Honor.

MR. ROGERS: Nothing from the defendant, Your Honor.

THE COURT: Okay. Thank you. See you in the morning.

(Proceedings concluded at 4:32 p.m.)

C E R T I F I C A T E

I, JENNIFER A. PANCRATZ, do hereby certify that I am duly appointed and qualified to act as Official Court Reporter for the United States District Court for the District of Arizona.

I FURTHER CERTIFY that the foregoing pages constitute a full, true, and accurate transcript of all of that portion of the proceedings contained herein, had in the above-entitled cause on the date specified therein, and that said transcript was prepared under my direction and control.

DATED at Phoenix, Arizona, this 28th day of September, 2018.

s/Jennifer A. Pancratz
Jennifer A. Pancratz, RMR, CRR, FCRR, CRC